

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SINCLAIR PHARMA LIMITED, SINCLAIR PHARMA US, INC., VIORA,
INC., EMA AESTHETICS, LTD., AND AESTHETIC MANAGEMENT
PARTNERS, LLC AND AESTHETIC MANAGEMENT PARTNERS, INC.,

Petitioners,

v.

HYDRAFACIAL LLC

Patent Owner.

Case No. IPR2025-00145
U.S. Patent No. 11,865,287

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: August 25, 2025

By:  Karl R. Leinsing
2025.08.25 19:46:58
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Karl R. Leinsing, MSME, PE

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1. I, Karl Leinsing, am making this declaration at the request of Patent Owner HydraFacial LLC in the matter of the Inter Partes Review No. IPR2025-00145 of U.S. Patent No. 11,865,287 (“the ’287 patent”). I understand that this declaration is being submitted in this proceeding as Exhibit 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	Sinclair’s Petition for Inter Partes Review
1001	U.S. Patent No. 11,865,287
1002	Excerpts of File History for U.S. Patent 11,865,287
1003	October 8, 2024 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”)
1008	U.S. Patent No. 6,684,880 (“Trueba”)

Exhibit or Paper No.	Description
2005	2016-05-09 Order Granting Plaintiff's Motion for Summary Judgment, <i>Edge Systems LLC v. Aguila</i> , 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, <i>Edge Systems LLC v. Aguila</i> , 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, <i>Edge Systems LLC v. Aguila</i> , 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
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)

Exhibit or Paper No.	Description
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)
2048	Excerpts from the 2003 Bloomsbury Dictionary of Science and Technology 1 st Ed.
2049	Excerpts from the 2004 Bloomsbury English Dictionary 2 nd 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

Exhibit or Paper No.	Description
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)
2074	Elite Device Photo
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

Exhibit or Paper No.	Description
2091	Allegro Device Part Photo
2092	Tower Device Part Photo
2093	Elite Device Photo
2094	Elite Device Part Photo
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

Exhibit or Paper No.	Description
2111	Handpiece Photo
2112	Handpiece Photo
2113	Syndeo Engineering Report [SEALED]
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

Exhibit or Paper No.	Description
2135	Elite Device Photo
2136	Elite Device Photo
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 <i>Edge Systems LLC v. Raphael Newton Aguila</i> , 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 <i>Edge Systems LLC v. Raphael Newton Aguila</i> , 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 (<i>Markman</i> 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)

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, wound closure device, among others. I also have extensive experience with machine design that use pneumatic valves, regulators, tubing, and fittings, in addition to actuators, motors, vacuum pumps, and various automated mechanisms. One example is a machine that uses these components to create a knitted endometrial ablation array for the NovaSure device. I am named as an inventor on U.S. Patent 6,158,250 covering this technology.

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, valve mechanism, and adapters that attached to the distal end of the device.

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. Exhibit 2002 is a true and correct copy of my *curriculum 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 '287 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 if it falls within the field of the inventor's endeavor or 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. In other words, a reference discloses or teaches a claim limitation if a POSITA would, at the relevant time, interpret the reference as expressly, implicitly, or inherently disclosing the claim limitation. I further understand that a reference does not need to use the exact language of the claim to disclose a claim limitation.

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 '287 Patent.

21. I understand that the level of ordinary skill in the art for the '287 patent is determined as of December 30, 2005, which is the earliest effective filing date of the patent. I also understand that Petitioners have not alleged that the '287 patent is not entitled to the December 30, 2005 effective filing date.

22. In my opinion, a POSITA for the '287 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. In fact, I was a POSITA at the relevant time. 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.

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 ’287 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 stated above.

Pet., 3.

25. Petitioners’ definition of a POSITA ignores important knowledge of medical implications that would have been necessary for a POSITA to assess the

obviousness of a proposed combination. Therefore, I disagree with Petitioners' definition.

26. Nevertheless, I alternatively applied Petitioners' definition of a POSITA and determined that my opinions are the same under either definition. Specifically, under either definition, the challenged claims of the '287 patent would not have been obvious.

IV. BACKGROUND AND PATENTED TECHNOLOGY

A. The Skin Cycle

27. The skin is comprised of three layers of tissue including the epidermis, the dermis, and the subcutaneous layer or hypodermis. The skin covers the entire external surface of the body and is the body's largest organ.

28. As skin cells die, they flake off the superficial epidermis and are replaced by new cells from the deeper layers of the epidermis. During the maturation process, the new cells move from immature cells of the stratum basale (stratum germinativum) to the most superficial layer of the epidermis – the stratum corneum. As the new cells “move upward”, they harden, desiccate, and die.

29. Microscopically, the stratum corneum consists of 15-20 layers of keratinized, flattened cells that are devoid of nuclei and cell organelles and as such are not alive. Maturational senescence is the process of a newly formed cell changing to a cell of the stratum corneum. The final result of maturational

senescence is flaking, scaling and desquamation of epidermal cells. Daily life activities can wear away or wash away these cells.

30. Skin maturation cycles can vary based on age. For example, the skin maturation cycle takes about 14 days for an infant. In contrast the skin maturation cycle can take over 50 days for an adult. Slower cycles of cell production and replacement can result in dead cells accumulating on the surface causing blunting, and loss of radiance or luster. This can be caused by discolored and irregular cells becoming trapped on the surface of skin, which in turn can cause spots and discoloration.

31. Age along with other factors such as (but not limited to) environmental, hormonal, nutritional, illness, sun exposure, and stress can affect the skin cycle.

32. Skin rejuvenation treatments are used to maintain healthier, softer and more luminous looking skin. These types of treatments can remove dead cells from the surface. By removing the dead cells, the skin maturation process can be sped up and in turn reveal a more healthy, vibrant and glowing skin.

B. Prior Art Microdermabrasion

33. Skin rejuvenation treatments include treatments such as laser resurfacing, mechanical resurfacing and chemical peels. I briefly discuss mechanical resurfacing techniques such as microdermabrasion and hydrodermabrasion, as these are the techniques described in the '287 Patent.

34. Skin rejuvenation treatments stimulate collagen growth. Collagen and elastin are responsible for giving skin its firmness and elasticity. However, as we age, the body's natural production of collagen and elastin declines, eventually leading to wrinkles, sagging skin, and dull skin. By stimulating collagen growth, skin rejuvenation treatments improve skin smoothness and sagging.

35. Microdermabrasion is one type of skin rejuvenating treatment. A microdermabrasion procedure or treatment uses a method of mechanical exfoliation. An instrument is used to remove the most superficial layers of dead skin cells from the epidermis. A microdermabrasion treats areas of the skin by using an instrument with an abrasive tip that directly contacts the skin, or by applying fine abrasive particles between the tip and the skin. When applying abrasive particles, often aluminum oxide crystal particles are used, having sharp edges that provide the abrasive effect when propelled at the skin. Ex. 1013 at 76 (native page number). In many cases a vacuum source is used to remove the exfoliated skin cells and used particles. *Id.* However, microdermabrasion has many drawbacks.

36. For example, microdermabrasion is inappropriate for sensitive skin and can be a painful experience. *See* Ex. 2012 (Loesch, et al., Skin Resurfacing Procedures: New and Emerging Options, Clinical Cosmetic, and Investigational Dermatology, 2014:7, 231-241) at 238. Due to its harsh nature, microdermabrasion often leaves patients with red skin, dryness, and photosensitivity. *Id.*

37. In addition, microdermabrasion through the application of fine abrasive particles is associated with risks. In such treatments, crystals such as aluminum oxide crystals are propelled at the face. Chronic aluminum oxide exposure has been associated with respiratory disease, pulmonary fibrosis, interstitial pneumonia, and papillomas of the larynx and trachea. *See* Ex. 2013 (Kempiak, et al. Superficial Chemical Peels and Microdermabrasion for Acne Vulgaris, *Senin Cutan Med Surg*, 27:212-220 (2008)) at 2019. In addition, treatment may be complicated by eye irritation if crystals get in a patient or practitioner's eyes. *Id.* At a minimum, eye protection must be worn, limiting a practitioner's ability to treat fine lines and wrinkles near the eyes.

38. The '287 patent expressly distinguishes the technology disclosed therein from prior-art microdermabrasion technology. It explains that microdermabrasion "refers generally to a procedure in which the surface of the skin is removed due to mechanical rubbing by a handpiece emitting a stream of sand or grit" which may contain "crystals of aluminum oxide, sodium chloride, or sodium bicarbonate" to wear away "cell layers of the skin." Ex. 1001, 1:65-2:7. The patent further explains that the "momentum of the grit tends to wear away two to three cell layers of the skin with each pass of the handpiece." *Id.*, 2:3-5. One problem with microdermabrasion is it "removes moisture from the skin." *Id.*, 2:16. To mitigate this problem, "the procedure is always followed by the application of moisturizing

creams.” *Id.*, 2:17-18. But “the moisturizing elements only work as deep as the active ingredients can passively migrate through the remaining epidermis.” *Id.*, 2:19-22.

39. In contrast to microdermabrasion’s stream of sand or grit, the ’287 patent not only discloses replacing sand or grit with a fluid, but it also discloses an automated multi-serum system for treating skin that “deliver[s] **fluid** from at least one of the **plurality of fluid sources** to the handpiece assembly.”¹ *Id.*, 2:34-35. Consistent with this distinction, the claims of the ’287 patent do not cover prior-art microdermabrasion treatments that solely use dry particles. Rather, every claim of the ’287 patent recites at least two containers of **fluids** for treating the skin. The ’287 patent also describes and claims a novel and non-obvious automated system that allows a clinician to select from multiple different treatment fluids to connect to the handpiece for application to the patient’s skin during treatment.

C. HydraFacial and Hydrodermabrasion

40. The ’287 Patent, and the commercial HydraFacial devices, revolutionized the field by creating a market for hydrodermabrasion. Hydrodermabrasion uses instruments and serums to exfoliate skin. Hydrodermabrasion is less harsh on a patient’s skin as compared to

¹ I supply the emphasis herein unless otherwise noted.

microdermabrasion (sand blasting). In addition to exfoliating the skin, hydrodermabrasion instruments, like those described in the '287 Patent, simultaneously and/or sequentially deliver multiple treatment serums or solutions to the exfoliated skin. The use of liquid during the treatment allows for smoother movement of the device and offers immediate relief and hydration to treated skin. By simultaneously exfoliating, opening pores, and administering treatment fluids, patients receive deeper penetration of treatment fluids, resulting in more effective treatments. Simultaneously abrading while delivering serums to the skin surface allows patients to leave a treatment with less redness and irritation.

41. Hydrodermabrasion with abrading structures has proved particularly effective. It has also reduced the risk of harm to both patient and practitioner by removing the need for crystals and providing a device that suctions away dead skin and debris, reducing unwanted dust, while simultaneously hydrating the skin and enhancing treatment serum penetration.

42. Microdermabrasion is performed using an abrading surface, sometimes covered with a layer of diamond grit, without simultaneous administration of fluids. Such treatments are painful and could even damage the skin. Hydrodermabrasion results in reduced side effects compared to microdermabrasion, such as sensitivity and redness, which can result in a better treatment outcome. Lastly, hydrodermabrasion provides a more pleasant and relaxing experience for a patient

because it is less painful. The patient is also presented with multiple treatment fluids and moisturizers that can be tailored specifically to them and automatically delivered to provide a quick, enjoyable skin treatment. Taking all of these factors into consideration, it is my opinion that hydrodermabrasion, as described in the '287 Patent, has proven to be a significant advancement in skin rejuvenation treatments.

43. HydraFacial markets and sells its hydrodermabrasion systems throughout the United States to end users such as dermatologists, plastic surgeons, cosmetic physicians, and aestheticians at medical spas. Below is HydraFacial's latest flagship product, the Syndeo, along with the three-treatment solution (serum) bottles and the cleaning solution bottle.



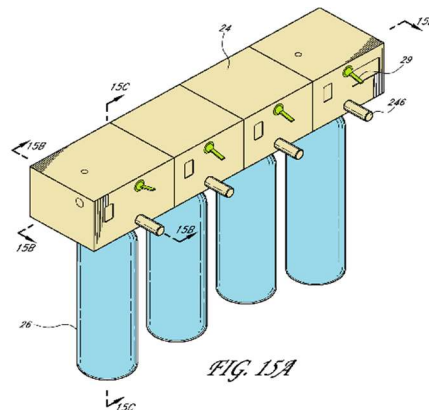
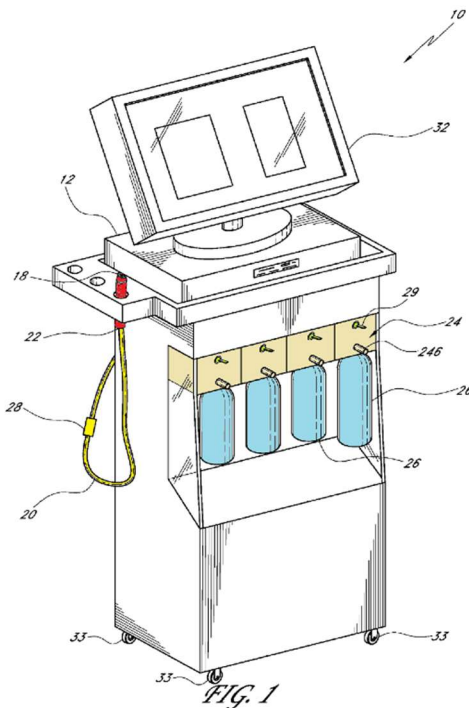
44. I am aware the HydraFacial products include red and blue light therapy handpieces, but they are generally considered to be insignificant add-on components to the HydraFacial system as a whole. For example, the effects of red and blue light therapy can be achieved using less expensive light therapy devices as opposed to a HydraFacial product. *See, e.g.,* Ex. 2015 (handheld red, blue and infrared light treatment device sold for \$299).

45. In addition to providing improved and less painful treatment, the '287 Patent, which is also incorporated into the HydraFacial devices, improved the

rapidity with which practitioners could perform treatments, by allowing numerous serums to be available for use at the touch of a button. The improved rapidity of treatment is due to the ability of practitioners to put different serums in the multiple bottles on the device and switch between them. This not only increased efficiency in changing serums, but also avoided the need for a manual application of products.

D. The Patented Technology

46. The '287 patent discloses a skin-treatment system that applies treatment fluids to a person's skin while simultaneously suctioning spent treatment fluid away from the skin and into a waste container. Ex. 1001, 5:63-6:2, 7:59-8:5. The user can select a desired treatment media from multiple treatment-fluid containers (shown in blue below). *Id.*, 6:21-30, 15:61-63, 17:17-29.



Ex. 1001, Figs. 1, 15A (annotated).

47. HydraFacial's patented invention can also include a block (shown in beige above). The block can connect to the fluid containers of the system and, when there is at least one container connected to the system, the block is in fluid communication with the handpiece (shown in red above) through a supply conduit (shown in yellow above). *Id.*, 2:30-35, 3:57-59, 5:28-31, 6:22-24, 17:17-29, 18:6-18. The patented system also contains a vacuum source which, when the user places the handpiece tip against the skin, creates an area of negative pressure inside the tip. *Id.*, 11:4-10. That negative pressure pulls the patient's skin against the handpiece tip. *Id.*, 11:4-13. The negative pressure also draws treatment fluid from the selected container while simultaneously suctioning waste into a waste container. *Id.*, 7:59-8:5, 11:4-17. The multiple treatment-fluid containers allow the physician or esthetician using the device to selectively draw treatment fluid from the containers and thereby provide a customized, multi-step treatment for each patient. *Id.*, 6:24-37, 16:34-59.

48. The '287 patent describes the same treatment fluids used in the Syndeo and HydraFacial's other commercial systems: "active-4TM" as the cleansing and exfoliating serum (*id.*, 15:61-16:6); "Beta-HDTM" as the salicylic acid extraction serum (*id.*, 16:6-16:14); and "Antiox-6TM" as the antioxidant hydration serum (*id.*, 16:14-23).

V. CLAIM CONSTRUCTION

49. In my view, no express claim construction is necessary to assess the issues I was asked to analyze. I have applied the plain and ordinary meaning in view of the claim language, specification, and prosecution history to each claim term relevant to my analysis. However, I note that based on the plain meaning of the terms “treatment fluid,” “treatment material,” and “fluid”/“fluids” in the claims, dry abrasive particles are not within the claim scope.

A. “treatment fluid” (claims 1 and 37)

50. Claims 1 and 37 of the ’287 patent recite a system for treating skin that includes at least two containers that each contain a “treatment fluid.” I was asked to evaluate whether the plain and ordinary meaning of “treatment fluid,” in the context of the ’287 patent, encompasses dry solid particles like those used in the Greenberg reference Petitioners rely on for Grounds 2A and 2B. For the reasons set forth below, I conclude that the plain and ordinary meaning of “treatment fluid” does not encompass such dry solid particles.

51. I understand that Petitioners do not propose any construction for “treatment fluid.” Pet., 2-3. However, Petitioners interpret the following paragraph as capturing dry “abrasive particles” within the term “fluid.”

As used herein, the term “treatment material” is a broad term and includes, but is not limited to, medicament, a substance tending to flow or conform to the outline of its container such as fluid, gas, liquid (e.g.,

serums, water, saline, etc.), gel, fluidized material, additives, and/or a plurality of fine solids. The general term “fluid” is used throughout synonymously with the term “treatment material” and is to be given the same broad definition.

Ex. 1001, 5:47-54 (cited by Pet., 68). Petitioners focus on the statement about “a plurality of fine solids” to allege that “abrasive particles” in the prior art can be a “treatment fluid” in the context of the ’287 patent. Pet., 68.

52. In my opinion, Petitioners’ suggestion that a collection of dry solid particles can be a “treatment fluid” is incorrect. A POSITA would have understood that a collection of dry solid particles standing alone is not a “treatment fluid” under the plain and ordinary meaning of that term in view of the specification and in view of the patent’s prosecution history. More specifically, Petitioners’ interpretation is incorrect for at least four reasons.

53. First, Petitioners’ interpretation is inconsistent with the well-understood meanings of the two common words “treatment” and “fluid.” The ’287 patent does not define the composed term “treatment fluid.” However, a POSITA would have readily understood the meaning of “treatment fluid” because it is composed of two common, ordinary words with straightforward meanings. The term “fluid” does not refer to a solid. And the term “treatment” is an adjective indicating, in the context of the ’287 patent, that the “fluid” is used for a skin

treatment. Therefore, in my view, Petitioners' suggestion that a collection of dry solid particles can be a "treatment fluid" is incorrect.

54. Second, the patent specification supports my opinion that "treatment fluid" does not include dry abrasive particles. As explained above, the specification expressly distinguishes prior-art microdermabrasion using dry particles such as sand or grit to wear away skin from embodiments of the invention, which "deliver *fluid* from at least one of the *plurality of fluid sources* to the handpiece assembly." Ex. 1001, 2:34-35. In my opinion, A POSITA would have understood that the inventors claimed the use of treatment *fluids* to distinguish over prior-art microdermabrasion treatments that solely used dry particles such as sand and grit. Indeed, the patent distinguishes "wet" and "dry" modes of operation, explaining that the "wet" mode applies treatment materials to the skin, but the "dry" mode does not:

During some skin treatment procedures, treatment materials from multiple containers 26 are sequentially or simultaneously applied to the patient's skin during a "wet" mode of operation. ... In some embodiments, the console 12 can be used for a "dry" mode of operation. That is, the console 12 can be used to exfoliate skin, for example, without [sic: while] delivering little or substantially no treatment fluid.

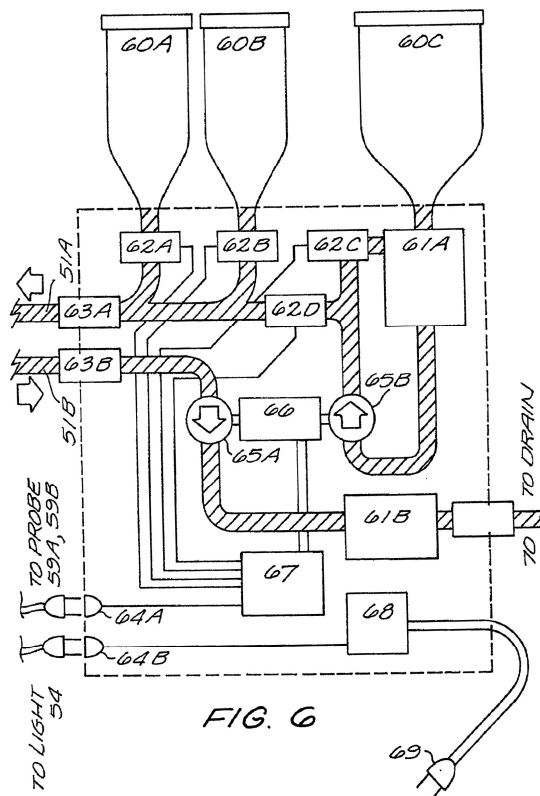
Id., 6:27-35. That the inventors described the mode using treatment materials as "wet" and the one using little or substantially no treatment fluid as "dry" demonstrates that the treatment fluids are not dry solid particles.

55. Further, the '287 patent also indicates, “During wet mode, fluid can be passed out of the tip 34 onto the patient’s skin.” *Id.*, 13:21-22. It goes on to explain that explain that the wet mode promotes **hydration** (*Id.*, 13:21-23), while dry mode “can be used for **non-hydration** procedures and may require less post-procedure clean up” (*Id.*, 13:31-33 (emphasis added)). The specification also explains:

Fluid traveling down the longer pathway is in contact with the person’s skin 80 for a longer period of time. Thus, tighter spirals lead to increased contact time between the fluid and the skin 80. These longer contact times can increase the effectiveness of the fluid because the skin can **absorb an adequate amount of active ingredients** of the treatment material. Fluid retention time on the patient’s skin can be increased to **increase hydration, serum retention, and the like**.

Id., 10:9-17 (emphases added). Thus, the identified functions of longer fluid contact times—absorption of ingredients, hydration, and serum retention—are not functions performed by solids. Finally, the specification lists numerous examples of fluids—including serums, hydration agents and additives, acids, extracts, and other substances—that are undoubtedly liquids, not solids. *Id.*, 15:61-16:33.

56. Regarding the prosecution of the '287 patent, I understand that the Examiner cited the Coleman reference (Ex. 2011) as prior art to the then-pending claims. Ex. 1002, 196-204. The Examiner relied on Figure 6 of Coleman:



Ex. 2011, Fig. 6 (cited by Ex. 1002, 197). Coleman calls each of elements 60A, 60B, and 60C a “reservoir” containing a different substance:

Reservoir 60A is used to contain a benign abrasive; reservoir 60B is used to contain a chosen medicinal component or combination of medicines; and reservoir 60C is used to contain the sterile water.

Ex. 2011, [0058]. Coleman gives three examples of benign abrasives: “rock salt, ice, and hardened starch.” *Id.*, [0015]. Thus, a POSITA would have understood the “benign abrasive” contained in reservoir 60A to be a collection of solid particles.

57. The Examiner found reservoirs 60B and 60C are containers containing two different treatment fluids. Ex. 1002, 197. However, with respect to a dependent claim requiring *three* containers containing treatment fluid, the Examiner found

“Coleman fails to disclose that all three containers contain fluid.” *Id.*, 203. The Examiner explained container 60A “contains abrasive material.” *Id.* Thus, the Examiner found Coleman’s “abrasive material”—solid particles such as rock salt, ice, or hardened starch—is not a treatment fluid. Based in part on that finding, the Examiner found the dependent claim allowable if rewritten in independent form. Ex. 1002, 201-204.

58. Petitioners do not provide any evidence that rebuts my opinions regarding the meaning of “treatment fluid” to a POSITA in the context of the patent specification and the prosecution history. I understand that Mr. Walbrink asserts a POSITA would have recognized Greenberg’s particles to be examples of the “fine solids” mentioned in the ’287 patent. Ex. 1003, ¶321.² But Mr. Walbrink does not provide any evidence to support this conclusion.

59. Third, Petitioners ignore context from the specification showing that “fine solids” are not dry particles standing alone. Petitioners’ cited paragraph lists “fine solids” among several examples—such as serums, water, saline, gel, fluidized

² 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-XV.” Ex. 1028, ¶20. I will cite only to Simon’s declaration for brevity unless I note otherwise.

material, and additives—that may be included in fluids, which tend “to flow or conform to the outline of its container.” Nothing in the specification suggests the term “fine solids” refers to a stand-alone collection of dry particles. A POSITA would have understood that “fluidized material,” as referenced in the cited paragraph, may include fine solid particles that are not fluid in their dry form but can be dissolved in a fluid. In the context of the ’287 patent—including its disclosure that *wet* operations use fluid, but *dry* operations do not—a POSITA would have understood that fluids may include “fine solids” dissolved in fluid, but that dry particles alone are not fluids.

60. Fourth, neither the cited paragraph nor anything else in the specification defines “treatment fluid” as recited by claims 1 and 37. The cited paragraph refers to “treatment material,” and, thus, provides no guidance as to the meaning of “treatment fluid,” much less broaden its ordinary meaning to include solids. In addition, the reference to “treatment material” is not a definition. It instead lists examples of substances that may be included in “treatment material” in certain contexts, but not in other contexts. A POSITA would not have considered the list of example substances as a definition in the specific context of the claimed invention, in which treatment fluid flows from containers to a fluidically connected handpiece for application to the skin. The list in the specification is overinclusive to encompass both the claimed context and a different context in which a solid treatment material

is contained in the tip of the handpiece and can be released and applied to the skin when it engages treatment fluid:

In alternative embodiments, the tips can carry deployable material. The structure 151 can be in the form of a cavity or pocket that contain and carry material that is released when it engages the treatment fluid. The material in the cavities can be any of the treatment materials disclosed herein, and can be in a solid form. For example, the cavities can hold lubricant or soap that is released when the tip is applied to skin.

Ex. 1001, 11:43-50. The specification further explains:

The protruding member 124 can optionally contain treatment material. For example, the protruding members 124 can be generally cylindrical members having a passageway or chamber 127 that holds treatment material. Thus, fluid can be used in combination with treatment material coupled to the tip 34.

Id., 12:14-19. One example of a solid treatment material used in this manner is a medicament that is a “hardened grit that can be imbedded on the surface of the tip 34” of the handpiece. *Id.*, 13:63-65. The specification states: “***If*** a fluid is used, the fluid can facilitate the release of the medicament from the tip 34.” *Id.*, 13:65-67.

61. Thus, the specification refers broadly to “treatment material” to encompass both the claimed context in which treatment fluid flows from containers to the handpiece for application to skin and the described but unclaimed context in which the tip of the handpiece contains a solid treatment material that may be

released when it engages treatment fluid. Nothing in the claim language, specification, or prosecution history suggests that the '287 patent's reference to "fine solids" broadens the term "treatment fluid" to cover a stand-alone collection of dry particles. At most, the reference to "fine solids" suggests solid particles dissolved in fluid.

62. For the reasons above, in my view, "treatment fluid" does not encompass a collection of dry solid particles.

B. "treatment material" (claims 11 and 22)

63. Claims 11 and 22 of the '287 patent use the term "treatment material" instead of "treatment fluid." On its face, the term "treatment material" seems broader than "treatment fluid." However, in my opinion, the surrounding language of claims 11 and 22 restrict the treatment material actually usable with the apparatus of claim 11 or system of claim 22 to treatment material that can flow from containers to a handpiece in fluid communication with the containers. Claim 11 recites a fluid control member "in fluid communication" with both first and second containers and a handpiece so that "the skin treatment apparatus is configured to selectively draw treatment material from the first container or the second container to the handpiece." Similarly, claim 22 recites that "the working end of the handpiece is configured to be placed in fluid communication with the first container or the at least one additional container through the collection lumen." While the specification does not

define the phrase “in fluid communication with,” it is a common, well-understood phrase describing a fluidic connection between objects where fluid flow is possible between the objects. Thus, for practical purposes, the treatment material of claims 11 and 22, like the treatment fluid of claims 1 and 37, excludes a “dry mode” or a collection of dry solid particles.

C. “fluid” / “fluids” (claims 16 and 25-26)

64. The term “fluid” (distinct from the term of art “fluid communication”) in claim 26 should be interpreted like “treatment material” in claims 11 and 22. *See* Ex. 1001, 5:52-54. As with claims 11 and 22, the surrounding language of claim 26 restricts the fluid usable with the system of claim 26 to fluid that can flow from containers to a handpiece in fluid communication with the containers. Claim 26 recites a system with a handpiece “in fluid communication with” a vacuum source and a block that receives fluid from three containers, such that the system may sequentially deliver fluid from the containers to the handpiece. Thus, for practical purposes, the fluid of claim 26, like the treatment fluid of claims 1 and 37, excludes a collection of dry solid particles.

65. Certain dependent claims include language that further confirms their scope does not encompass dry particles. For instance, claim 16 depends from claim 11 and recites that “the treatment material in the first container is a skin treatment fluid.” This requirement—that the treatment material be both in the first container

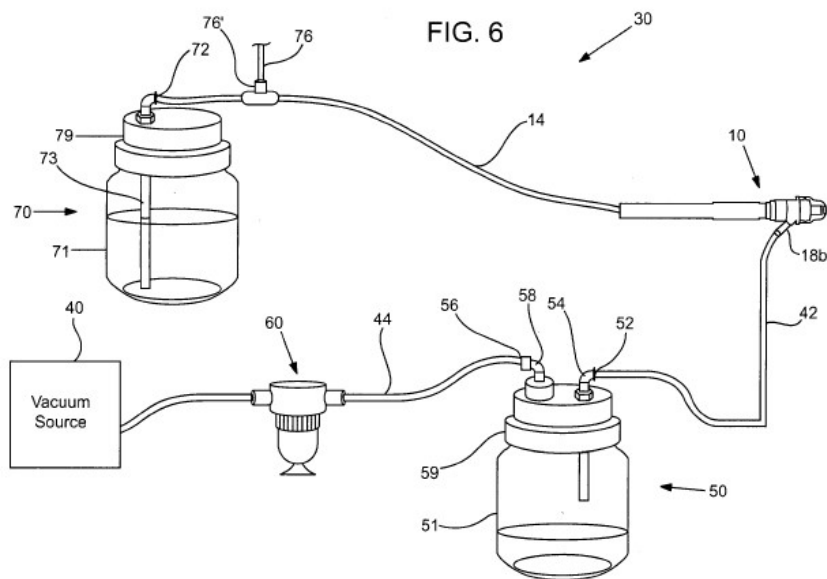
and a skin treatment fluid—excludes dry solid particles. Similarly, claim 25 depends from claim 22 and recites that “a flow of fluids from the first container and the at least one additional container.” The reference to fluids, in plural, flowing from the containers demonstrates that the treatment material is not composed of dry particles.

VI. PATENTABILITY OVER THE KARASIUK GROUNDS

66. 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 in Grounds 1A and 1B. In Ground 1A, Petitioners combine Karasiuk with Palmer to allege that all independent claims and some dependent claims would have been obvious. Pet., 1-2.

67. As shown in Figure 6 below, Karasiuk³ is a microdermabrasion device that draws liquid from just one container during a microdermabrasion treatment.

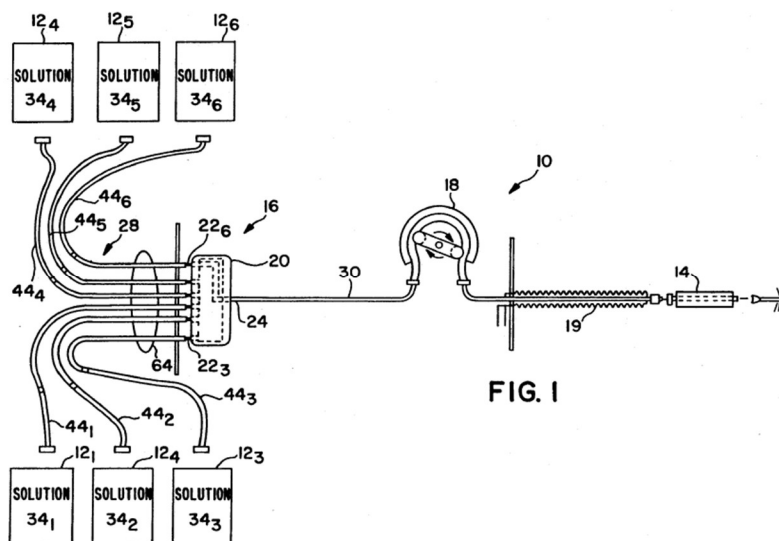
³ I recognize that Karasiuk describes the disclosed device as a “microdermabrasion device.” However, I understand that Karasiuk differs from traditional microdermabrasion because the device is not limited to using only solid dry abrasive particles.



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

68. In my view, Karasiuk does not disclose selectably connecting one of multiple skin-treatment containers to a handpiece. Nothing in Karasiuk suggests separately storing and applying different treatment fluids in a single microdermabrasion 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].

69. Palmer is an irrigation system used in periodontal procedures. Ex. 1005, 1:10-15. As such, Palmer delivers a “pulsed jet” 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 jet of solution, as shown in Fig. 1.



Id., Fig. 1.

70. 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 microdermabrasion 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.

71. Petitioners add Trueba in Ground 1B for dependent claims having computing device limitations, and for a single limitation in claim 1 already addressed in Ground 1A. Pet., 49-54. In my opinion, Trueba adds nothing of consequence to Ground 1B because Petitioners do not allege that Trueba discloses the limitations missing from Karasiuk and Palmer (Ground 1B). Trueba involves a micro jet dispenser that combines Hewlett-Packard's inkjet technology with pharmaceutical

administration. Ex. 1008, 1:7-12. Trueba provides “an applicator for inhalational or mucosal delivery of a bioactive composition using a jet dispenser, such as a piezoelectric or thermal jet dispenser.” *Id.*, 3:42-45. This jet dispenser “propels precise amounts of droplets from the dispenser toward a mucosal target.” *Id.*, 3:49-51.

A. Karasiuk and Palmer Do Not Disclose a Handpiece Connected to a Console

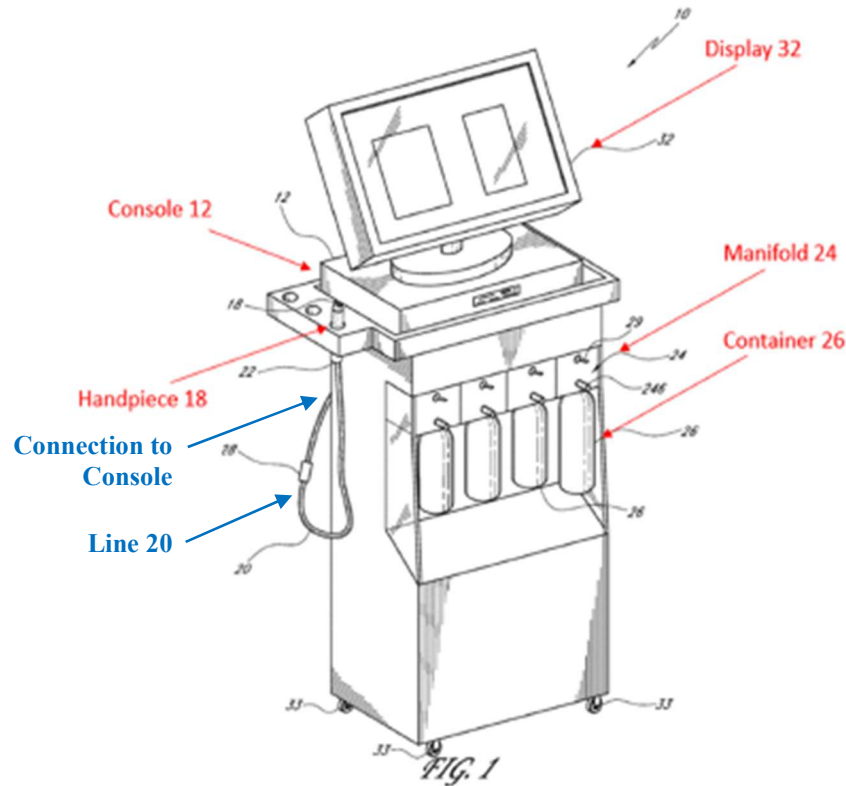
72. I was specifically asked to determine whether Karasiuk or Palmer discloses a handpiece connected to a console. Every claim of the '287 patent requires a handpiece (or handpiece assembly) connected to the console during operation. *See* Limitations 1.3, 11.3, 22.4, 26.5, and 37.5. This limitation is part of an all-in-one console system that automates the dispensing and vacuuming of multiple serums. For example, Limitation 1.3 recites:

wherein the block is: ... configured to be in fluid communication with the handpiece through a first conduit ***when the handpiece is connected to the console.***

Ex. 1001, 21:30-39. For the reasons explained below, in my opinion, neither Karasiuk nor Palmer discloses a handpiece connected to a console.

73. The '287 patent explains with respect to Figure 1 that the “treatment system 10 includes a console 12 and a handpiece assembly 18 connected to the

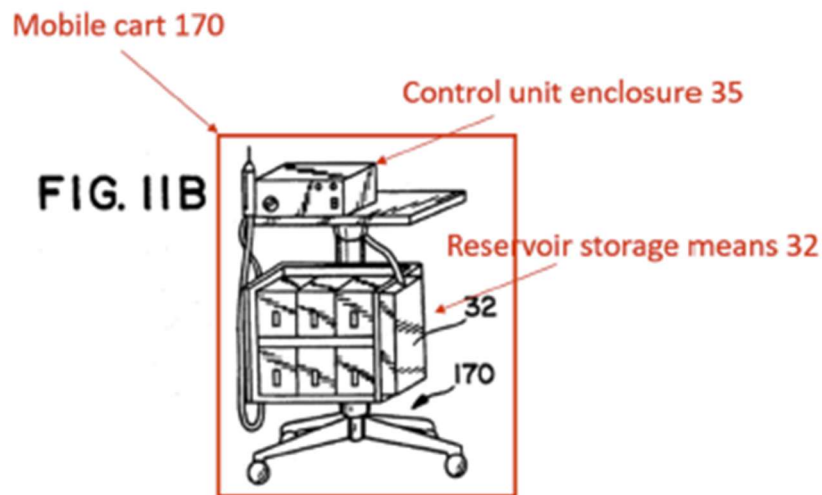
console 12 via a line 20.” *Id.*, 5:26-28. Petitioners’ annotated Fig. 1 shows this configuration:



Pet., 4 (’287 patent, Fig. 1)⁴. The specification explains that “[t]he line 20 can comprise one or more conduits extending between the console 12 and the handpiece assembly 18.” Ex. 1001, 5:65-67.

⁴ Blue annotations to the figures were added by me and the red annotations were added by Petitioners.

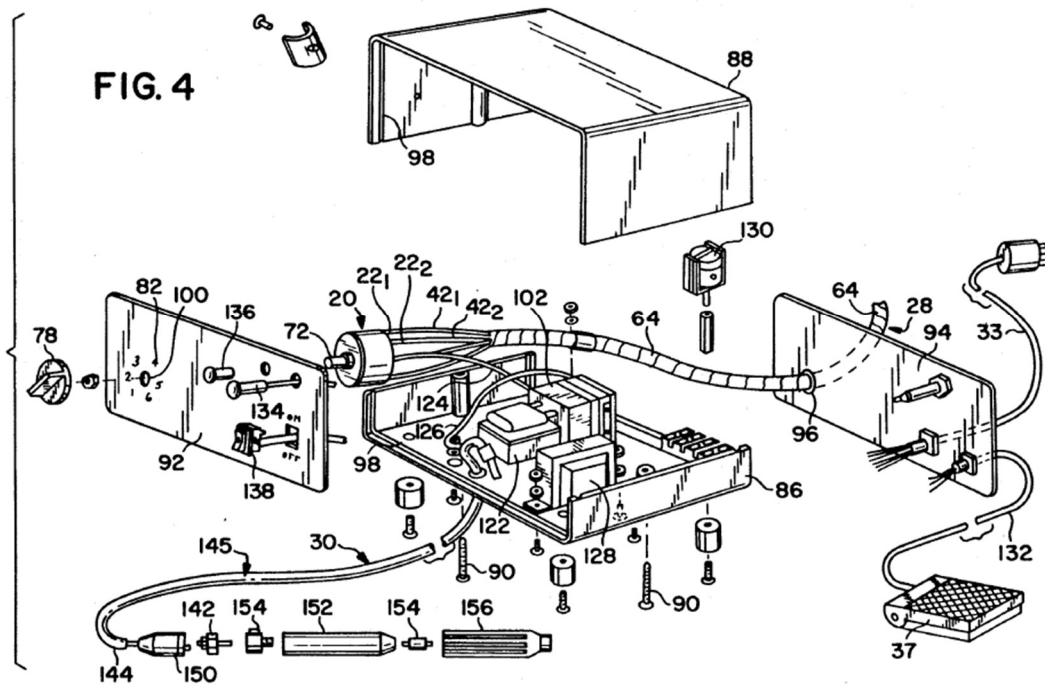
74. In my opinion, Petitioners fail to show that either Karasiuk's or Palmer's handpiece is ever connected to a console. Petitioners rely on Palmer's mobile cart 170, illustrated below, for the console.



Palmer, FIG. 11B

Petition 6 (“The Karasiuk-Palmer system includes a *console* in the form of, for example, ‘mobile cart 170.’” (emphasis by Petitioners)).

75. However, Palmer's handpiece is not connected to mobile cart 170 in Palmer. Instead, Palmer's handpiece is connected by tubing to “control unit enclosure 35.” Ex. 1005, 5:16-20. Control unit enclosure 35 is a modular component in Palmer's system. *Id.*, 3:9-14. Fig. 4, shown below, is an exploded fragmentary view of control unit enclosure.



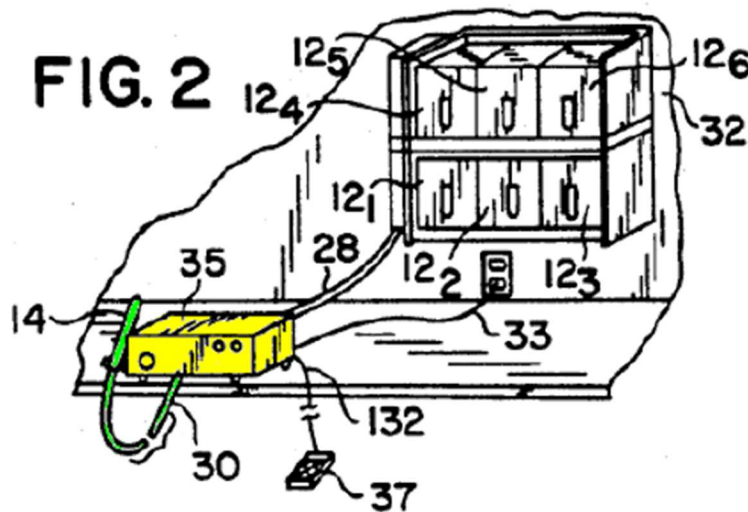
Id., Fig. 4, 4:19-21. Palmer explains that “[s]econd tubing means 30 couples the handpiece means 14 to the output of the pump within enclosure 35.” *Id.*, 5:16-18.

76. Fig. 7 shows the connection of the handpiece means to the bottom portion of control unit enclosure 35 in more detail:



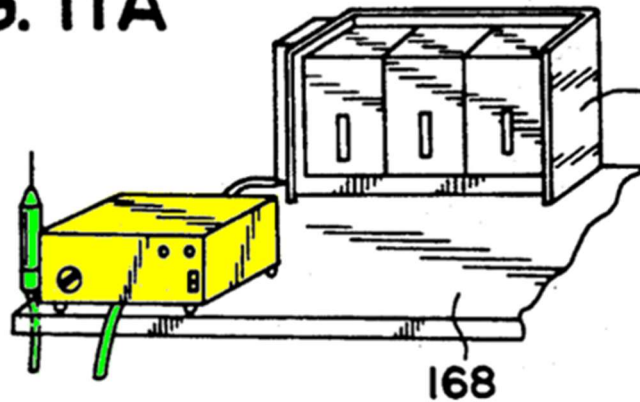
77. Palmer's control unit enclosure 35 and reservoir storage means 32 are modular components in Palmer's system. Palmer explains that the "modular means for storing solution reservoirs" and providing "substantial flexibility in setting up the system" are "the present invention." *Id.*, 3:9-14. The system's modular configuration is an "advantage[]" in the installation of the system." *Id.*, 9:58-10:2. To that end, Palmer describes placing the control unit enclosure 35 and reservoir storage means 32 in separate locations around the dental office. In each instance, handpiece means 14 is connected only to control unit enclosure 35.

78. Fig. 2 shows control unit enclosure 35 on a countertop with handpiece 14 attached, and reservoir storage means 32 hanging on the wall.

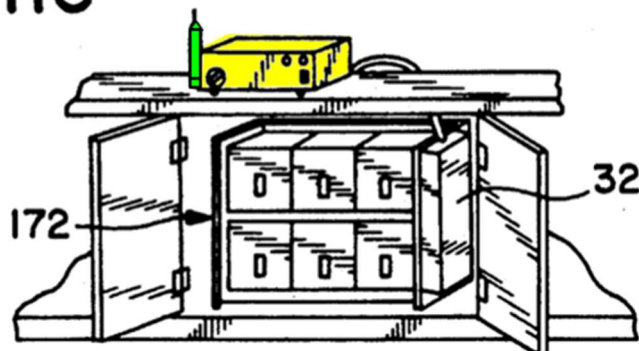


Ex. 1005, Fig. 2 (annotated), 5:10-13.

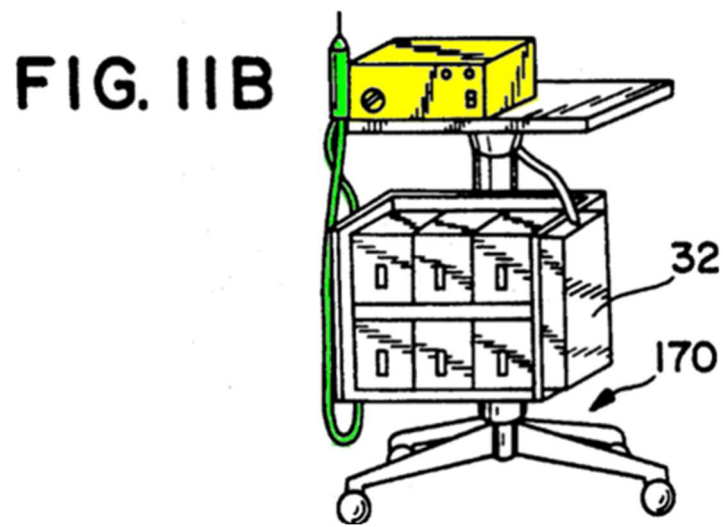
79. Fig. 11A shows both control unit enclosure 35 and reservoir storage means 32 on countertop 168.

FIG. 11A

Id., Fig. 11A (annotated), 9:66-10:2. Fig. 11C shows reservoir storage means 32 “in a cabinet 172 underneath a counter,” with control unit enclosure 35 on top of the counter.

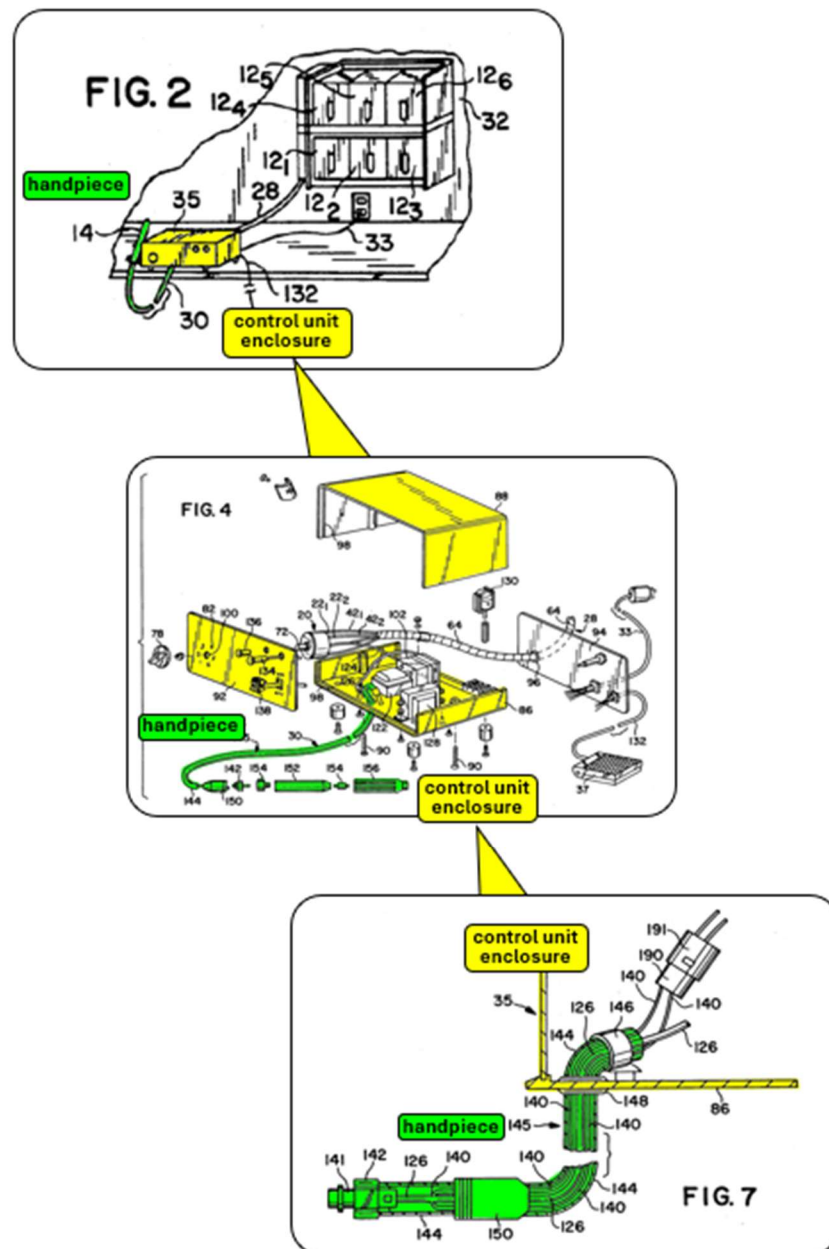
FIG. 11C

Id., Fig. 11C (annotated), 9:66-10:2. Similarly, Fig. 11B, cited by Petitioners, shows Palmer’s control unit enclosure 35 on a shelf on mobile cart 170 with the handpiece attached to control unit enclosure 35.



Id., Fig. 11B (annotated), 9:66-10:2.

80. The annotated figures below (Palmer's Figs. 2, 4, and 7) show that Palmer's handpiece is connected to the modular control unit enclosure 35 and not connected to Palmer's mobile cart 170.



Id., Figs. 2, 4, 7 (annotated); see also *id.*, 4:19-27.

81. Palmer explains with respect to Fig. 4 that “[s]econd tubing means 30 couples the handpiece means 14 to the output of the pump within enclosure 35.”

Id., 5:16-18. And with respect to Fig. 7, Palmer explains that “[t]he clear *handpiece*

tubing assembly, designated 145, **is clamped within enclosure 35** by a cable clamp 146 and passes through the bottom member 86 through a grommet 148.” *Id.*, 9:37-40.

82. Petitioners contend “a POSITA would have found obvious that Karasiuk’s device 10 (handpiece) is connected to ‘mobile cart 170’ (console), as illustrated in Palmer.” Pet., 20-21. However, Palmer’s handpiece is never connected to Palmer’s mobile cart that Petitioners allege is the console. And Petitions never explain why or how a POSITA would have connected Karasiuk’s handpiece to Palmer’s mobile cart in light of Palmer’s disclosure to the contrary. Petitioners point to Palmer’s Fig. 11B, but, as discussed above, that figure actually confirms Palmer’s handpiece is not connected to the mobile cart. Pet., 20-21. Petitioners’ expert, Mr. Walbrink, repeats Petitioners’ same argument nearly verbatim, without any additional evidence. Ex. 1003, ¶113 (“a POSITA would have found it obvious that the handpiece (e.g., Karasiuk’s device 10) is connected to the ‘mobile cart 170’ (console).”).

83. In my opinion, because Petitioners failed to show the proposed combination of Karasiuk and Palmer has its handpiece connected to a console, the claims would not have been obvious over Karasiuk and Palmer.

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

84. 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 microdermabrasion treatment. Pet., 8-9. 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.* However, neither “general knowledge” nor “Karasiuk’s disclosure” provides a motivation to use multiple types of treatment solutions *during microdermabrasion*, let alone to modify Karasiuk’s single-container system to add more containers and a “block,” “fluid control member,” or “collection lumen.”

1. “General Knowledge” Was Not a Motivation

85. The Petition includes no explanation of the “general knowledge” that would have supposedly motivated a POSITA to modify Karasiuk. It appears that Petitioners instead rely on analysis by Mr. Walbrink. Pet., 8-9 (citing Ex. 1003, ¶¶78-79). In my view, Mr. Walbrink’s “general knowledge” analysis is flawed for several reasons. Mr. Walbrink asserts that “multiple treatment solutions are desirable during microdermabrasion.” Ex. 1003, ¶79 (citing Burgess (Ex. 1013) and Lee (Ex. 1016)). But Mr. Walbrink’s cited evidence contradicts his assertion that treatment solutions are desirable *during microdermabrasion*. For example, the

Burgess section cited by Mr. 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. This makes sense because, as Burgess explains, the traditional application of microdermabrasion involves the use of “fine, sharp crystals” to sandblast the skin. *Id.*, 84. It would be antithetical to apply moisturizer during a microdermabrasion procedure that is blasting the skin with fine, sharp crystals. Mr. Walbrink himself agrees, in describing Burgess, that moisturizer is applied “when microdermabrasion ***is completed***.” Ex. 1003, ¶79. Thus, no treatment solution is applied ***during*** microdermabrasion, let alone multiple treatment solutions, as Mr. Walbrink alleges.

86. Next, Mr. Walbrink cites to Lee as “general knowledge,” but Mr. Walbrink misapprehends the reference when he alleges “Lee discloses delivering vitamin C during microdermabrasion.” *Id.* (citing Ex. 1016, 1). In fact, 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. 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 no

way does Lee provide any motivation to use multiple types of treatment solutions during microdermabrasion as Mr. Walbrink alleges.

87. 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.” Pet., 9 (citing Ex. 1003, ¶¶80-84). Petitioners cite just to Mr. Walbrink, but his testimony is unhelpful as it relates to, for example, Hewlett Packard’s jet dispenser system (Trueba) and multiple dental irrigation systems (Palmer, Armstrong, and Pond). It is unclear to me how incorporating a structure from any of these different devices would, as Mr. Walbrink and Petitioners claim, make Karasiuk’s microdermabrasion device more flexible or functional. *Id.* Using multiple containers 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. In my opinion, Petitioners’ reference to a generic advantage, such as flexibility and functionality, does not provide a POSITA with a motivation to modify Karasiuk because it lacks specific evidence why a POSITA would have made the modification.

88. Thus, in my view, Petitioners have failed to show that “general knowledge” provides a motivation to modify Karasiuk to include multiple containers with multiple types of treatment solutions.

2. “Karasiuk’s Disclosure” Was Not a Motivation

89. Petitioners also point to “Karasiuk’s disclosure” itself as a motivation to modify Karasiuk. But, like the “general knowledge,” the argument is flawed. There is no disclosure in Karasiuk of automating multiple types of treatment solutions from multiple containers in a microdermabrasion treatment, and Petitioners do not argue otherwise. The only Karasiuk disclosure that Petitioners cite is: (1) the types of compounds that can be added to 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., 8-9 (quoting Ex. 1004, [0024], [0047], [0061], [0070]). Mr. Walbrink cites and quotes these same passages from Karasiuk without further explanation. Ex. 1003, ¶¶78, 80.

90. 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.* 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.

91. 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 block and associated connections that allow selection of the treatment solutions. In my view, such broad and vague language would not have provided a specific motivation to modify Karasiuk in the manner Petitioners propose.

92. Thus, "Karasiuk's disclosure" contains no evidence of a motivation to modify Karasiuk's system to include additional containers with treatment fluids and a block to control the flow of treatment fluids.

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

93. 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., 9-10. But, as explained above, neither "general knowledge" nor "Karasiuk's disclosure" could have plausibly motivated a POSITA to investigate other references as Petitioners claim. Petitioners' entire foundation for a POSITA seeking out Palmer is erroneous.

94. The alleged “benefits” Petitioners have selected from Palmer are rooted in the needs of periodontal irrigation systems at the time, not any then-known microdermabrasion system. In my view, Petitioners use hindsight to assume, without evidence, that the same benefits would apply to Karasiuk’s microdermabrasion system.

95. 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., 9-10. 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.” Pet., 9-10 (quoting Ex. 1005, 1:30-53).

96. Palmer’s additional disclosure further informs a POSITA the sequential delivery was unique to periodontal irrigation systems, as part of 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 dental irrigation teachings to Karasiuk’s microdermabrasion skin treatment system, but the sequential delivery is clearly meant for periodontal irrigation systems. Pet., 10.

97. 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 the individual fluids. Therefore, Petitioners have not shown that microdermabrasion clinicians would have recognized any problem with Karasiuk’s single-container design in need of an automated multiple serum solution.

98. 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., 10). Palmer’s opinion that cleaning and refilling a dental-irrigation tank is a time-consuming, costly, and messy procedure is irrelevant

to Karasiuk's microdermabrasion procedure. Neither Petitioners nor Mr. Walbrink assert 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 structure to Karasiuk's device. In fact, 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.

99. 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., 10. 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, 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.

100. The fourth alleged benefit is “Palmer’s modular design to provide added flexibility, organization, and portability.” Pet., 11. But this supposed benefit is irrelevant to Petitioners’ proposed change from Karasiuk’s single-container design to a multi-container 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. *Id.*

101. Accordingly, 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 microdermabrasion before the priority date of the ’287 patent. While those in the field now understand the benefits of, e.g., sequential delivery in view of the teachings of the ’287 patent and the success of HydraFacial’s commercial embodiments of the ’287 patent, Petitioners present no evidence a POSITA would have appreciated those benefits at the time of the invention. Accordingly, in my opinion, the claims would not have been obvious in view of Karasiuk and Palmer.

C. Petitioners' Combination Would Render Karasiuk's Device Inoperable

102. Grounds 1A and 1B in the Petition rely on the combination of Karasiuk and Palmer. Pet., 1-2. 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.

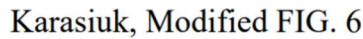
103. In my opinion, Petitioners' proposed combination of the Karasiuk and Palmer systems would render Karasiuk's system inoperable, because the resulting system: (1) has a vacuum source with a breather line that prevents material from flowing from the reservoirs; (2) has a tube diameter that is so small 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

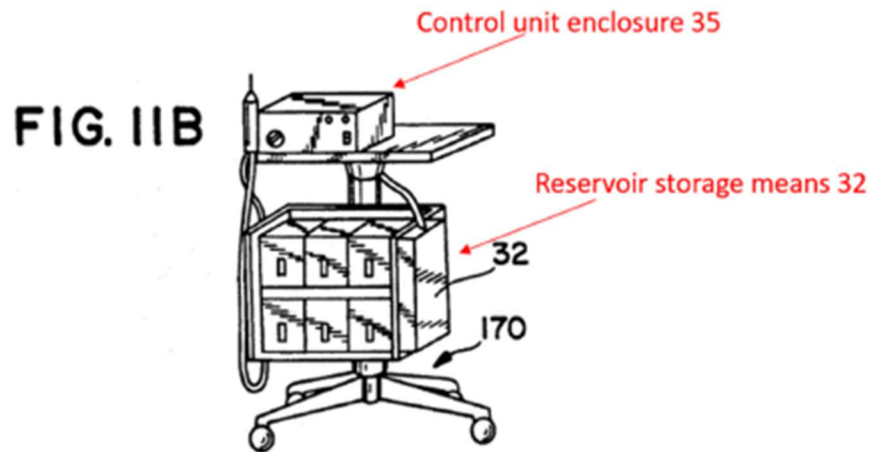
104. In Petitioners' proposed combination of the Karasiuk and Palmer systems, Petitioners contend that "Karasiuk's vacuum source would be used to pump treatment solutions from Palmer's multiple fluid containers and collect waste/debris." Pet., 7. That is, Petitioners remove Palmer's peristaltic pump 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".

105. 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." Pet., 7-8. 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 12₁ - 12₆. *Id.* I note that Petitioners also contend that this arrangement "achieve[s] benefits resulting from selection of different treatment solutions." Pet., 7-8.



107. Petitioners' Karasiuk-Palmer combination also involves adoption of Palmer's "mobile cart 170" for allegedly providing "increased portability and/or organization." Pet., 6. In Petitioners' combination, Palmer's mobile cart 170 houses the claimed multiple containers (Palmer's "solution reservoirs 12₁ - 12₆") 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., 13.

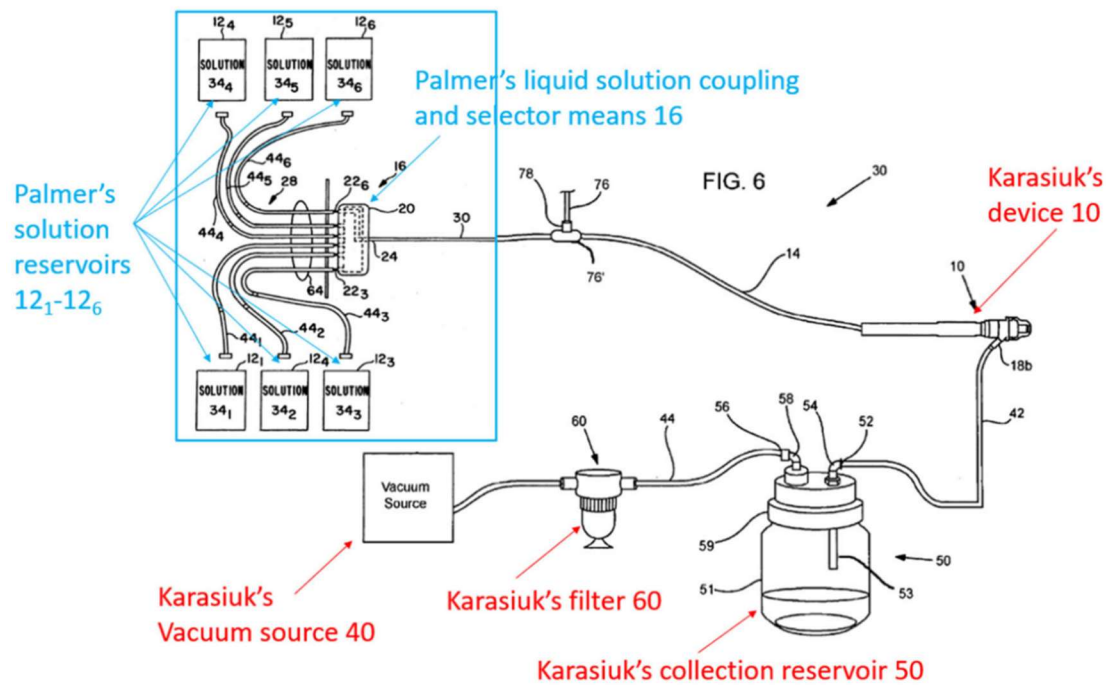
108. In the Karasiuk-Palmer combination, Palmer's solution reservoirs 12₁ - 12₆ are necessarily located below Karasiuk's breather line 76 and the handpiece 10. In this configuration, Karasiuk's vacuum source drawing only air through the breather line 76 along tube 14. The Karasiuk-Palmer combination 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 treatment material from Palmer's solution reservoirs 12 in Petitioners' proposed combination. This is like having a crack in a drinking straw. Thus, in my opinion, the Karasiuk-Palmer combination (small tubing with air vent) 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 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

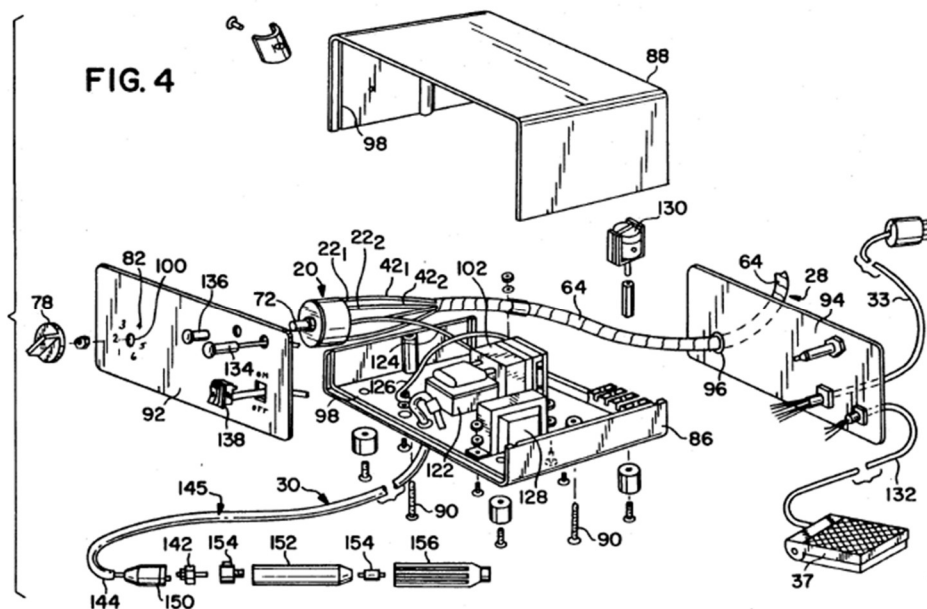
109. In my opinion, Palmer’s small-diameter tubing renders the combined Karasiuk-Palmer device inoperable.

110. 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.



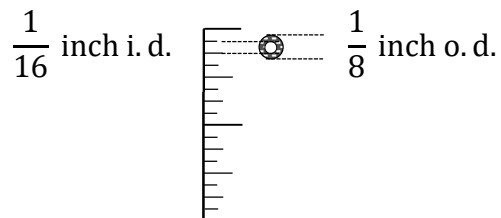
Karasiuk, Modified FIG. 6

Pet., 7, 16. 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:

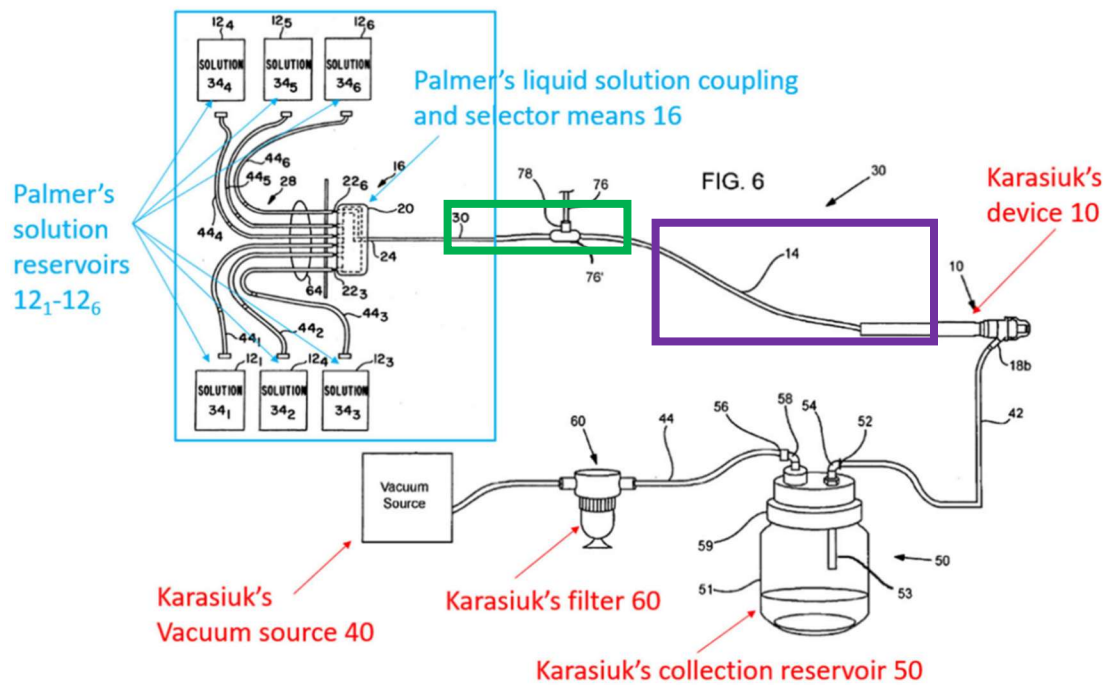


Ex. 1005, Fig. 4.

111. Palmer discloses that the system uses tubing with an outside diameter of $1/8^{\text{th}}$ inch and an inside diameter of $1/16^{\text{th}}$ 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 id.*, 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 $8 \frac{1}{2} \times 11$ -inch sheet of paper:



112. 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. *Id.*, 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. Further, Petitioners show in "Karasiuk, Modified Fig. 6" that the combined supply line uses a portion of Palmer's second tubing means 30 (tubing encompassed within the green box), which is not intended for viscous fluid flow. This means that it will be easier to draw fluid through Karasiuk's tube 14 (tubing encompassed within the purple box) and air from the breather line 76 than to pull fluid through the small tube 30 and tubes 44 of Palmer, making the whole system pull air instead of fluid and rendering the entire system inoperable. The Petition also makes no modification or mention of the supply line between Palmer's solution reservoirs 12₁-12₆, which, as I have discussed above, uses tubing with too small a diameter for viscous fluid flow. Ex. 1005, 2:32-36.



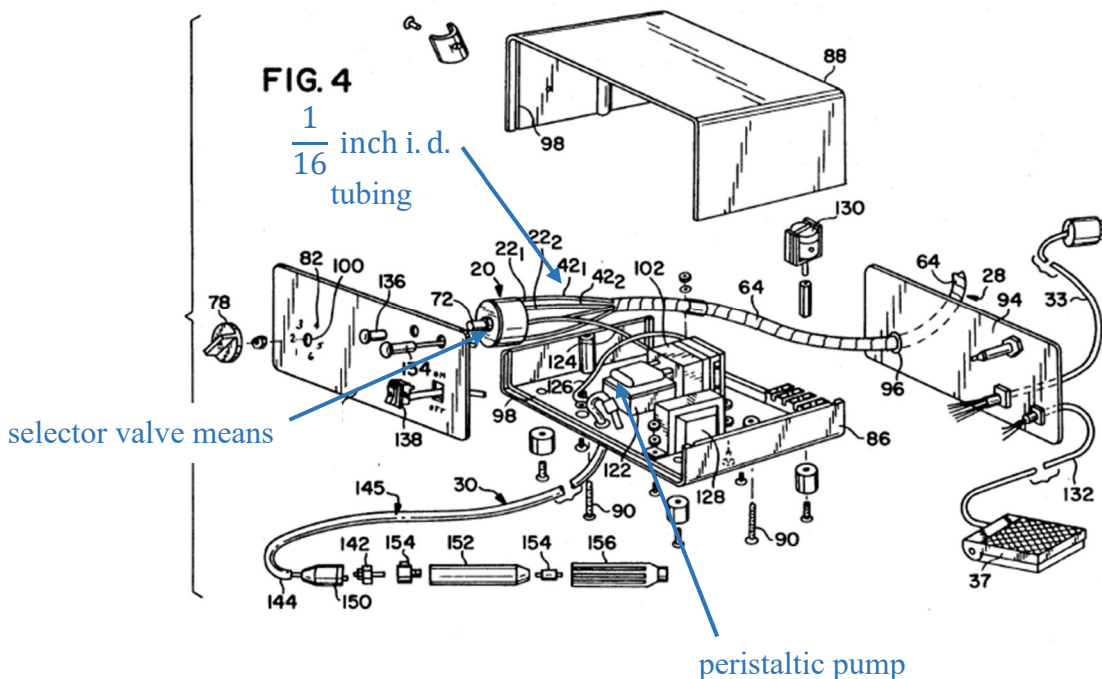
Karasiuk, Modified FIG. 6

Pet., 7, 16 (annotated).

113. 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. Ex. 1005, 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.

114. In my opinion, Palmer's system by itself supports the use of such small tubing between the solution reservoirs 12₁-12₆ and the selector valve means 20 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. The flexibility and compactness of the tubing is shown in Fig. 4:



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

115. In my opinion, Palmer's small-diameter tubing between solution reservoirs 12₁-12₆ and selector means 20 renders Petitioners' proposed combination of Karasiuk and Palmer inoperable.

116. 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 and by multiple factors more to the diameter 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.

117. 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).

118. 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.

119. I understand that certain dental applications, such as those involving irrigant solutions as in Palmer, benefit from high fluid velocity. I also understand that these dental procedures typically do not require high volumetric flow rates. In contrast, hydrodermabrasion procedures generally use relatively low volumetric flow rates (to conserve expensive serums) and derive little to no benefit from increased fluid velocity.

120. 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.

121. 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.

122. 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).

123. 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.

124. In my opinion, Palmer's tubing is so small that it does 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.

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

125. 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.

126. 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. *See* Ex. 1005, 11:30-34 (Palmer explaining that its peristaltic pump “serves as a natural check valve.”). Additionally, Palmer's selector valve means 20 is a one-inlet-to-one-outlet valve that serves as an uninterrupted pathway from the selected solution reservoir 12 towards the peristaltic pump.

127. 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. Therefore, Petitioners cannot meet their burden of showing that any claims of the '287 Patent would have been obvious over the cited prior art.

VII. PATENTABILITY OVER THE GREENBERG GROUNDS

128. I was asked to determine whether the challenged claims would have been obvious over the Greenberg grounds asserted in the Petition. I understand that in Ground 2A, Petitioners allege that all independent claims and some dependent claims would have been obvious over Greenberg alone.

129. Greenberg discloses a system for conducting microdermabrasion procedures using a handpiece to apply dry treatment materials to a targeted area of skin. Ex. 1006, [0013]-[0040]. 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.

130. 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. *Id.*, [0049].

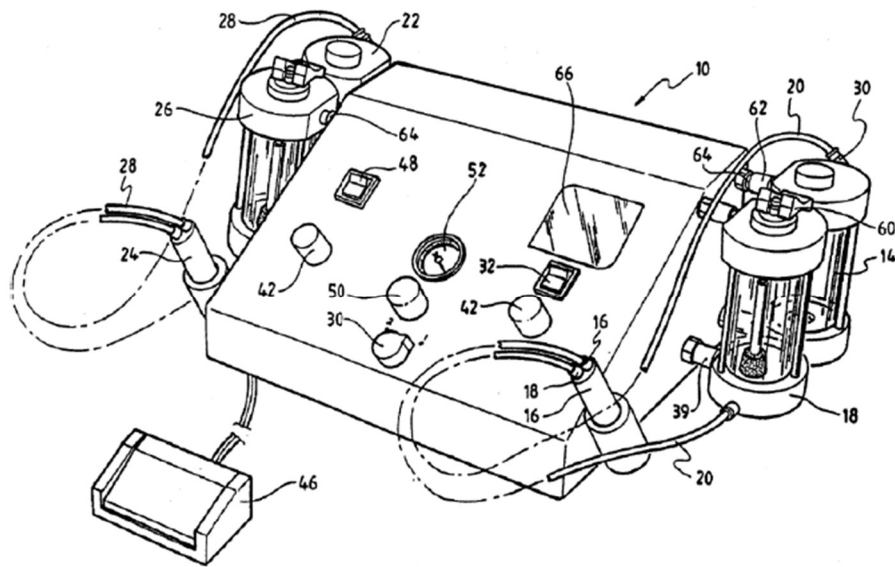


FIG 1

Id., Fig. 1.

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

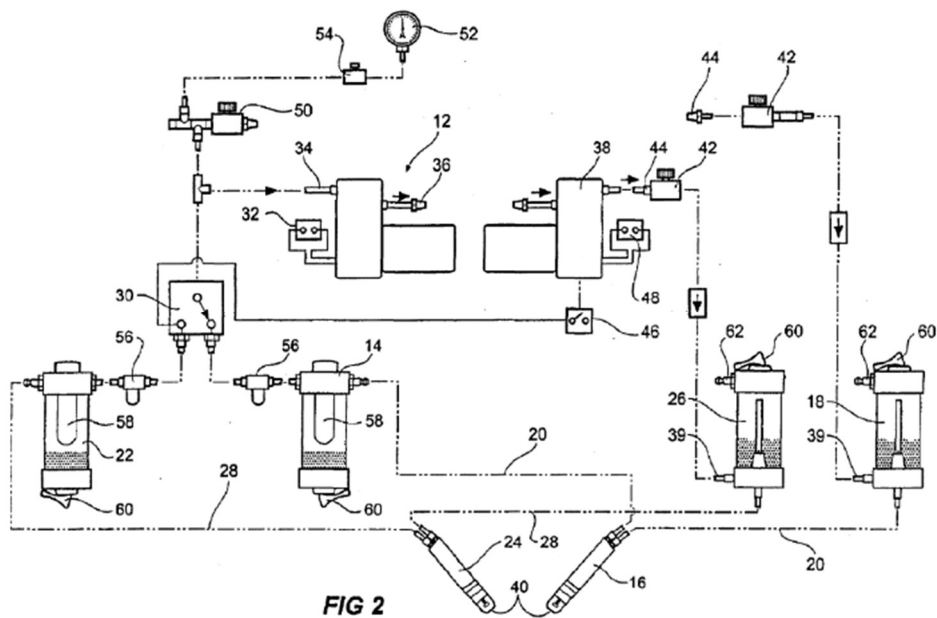


FIG 2

Id., Fig. 2

132. Greenberg discloses that the apparatuses of Figures 1-4 each has a vacuum source to draw spent 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.*, [0050]-[0051]. 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.*, [0077].

133. 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.*, [0065]. 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.*

134. 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.*, [0067]. It has a valve 30 that connects the supply containers 18, 26 to the different handpieces 16, 24.

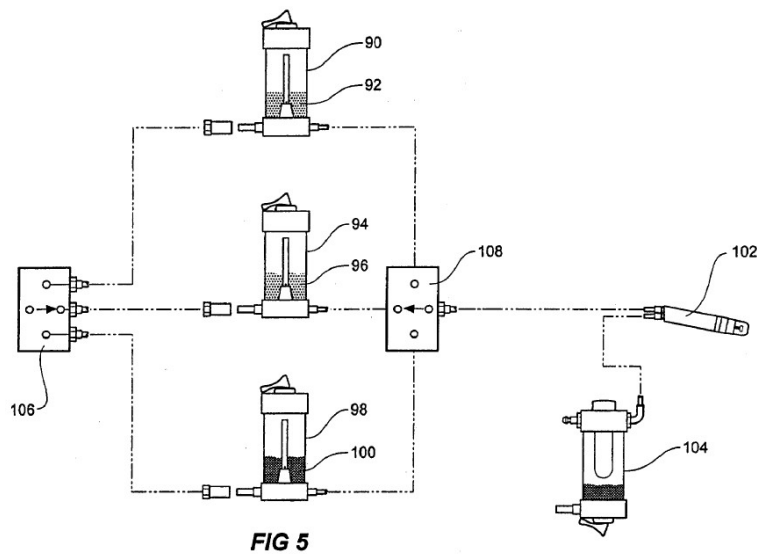
135. The version in Fig. 5 includes three containers 90, 94, 98, one recovery container 104, and one handpiece 102. *Id.*, [0077]. It employs two valves 106 and 108. Greenberg explains that “[a] supply container can be chosen to be in communication with handle 102 and recovery container 104 by the use 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. Greenberg’s Fig. 5 embodiment does not include any pneumatic source such as a compressor or vacuum.

136. Greenberg discloses another embodiment in Fig. 6 that includes one supply container and one recovery container. *Id.*, [0079].

137. I also understand that in Ground 2B, Petitioners allege that independent claim 1 and some dependent claims would have been obvious in view of Greenberg and Trueba. Pet., 91-92. Significantly, with respect to both grounds and all claims, Petitioners rely solely upon Greenberg as allegedly disclosing a device that applies multiple treatment materials or fluids to the skin. In Ground 1B, Petitioners allege Trueba discloses other claim limitations, but does not rely on Trueba for the multiple-treatment-fluid limitations. *Id.* Trueba involves a jet dispenser that combines Hewlett-Packard’s inkjet technology with pharmaceutical administration. Ex. 1008, 1:7-12.

138. For the reasons set forth below, it is my opinion that Petitioners fail to show that Greenberg, alone or in combination with Trueba, discloses or renders obvious the multiple-treatment-fluid limitations.



Ex. 1006, Fig. 4, [0073]-[0077].

A. Greenberg’s disclosure of microdermabrasion using dry particles does not disclose or make obvious the claimed hydrodermabrasion using treatment materials or fluids

1. Greenberg lacks the “treatment fluid[s]” of claims 1 and 37

139. Claim 1 recites “the first container contains a treatment fluid” and the “additional container contains an additional treatment fluid.” Similarly, claim 37 recites “first treatment fluid contained in the first container” and “second treatment fluid contained in the at least one additional container.” Greenberg does not disclose “treatment fluid.” It discloses “supply containers including particulates” or “different particles.” Ex. 1006, [0015], [0020], [0021]. Greenberg further discloses typical particles used in “a micro-dermabrasion machine,” including “[p]urely organic materials,” a “mixture of abrasive particles such as aluminum oxide mixed with organic materials,” or “[a]brasive particles that are coated with organic

materials.” *Id.*, [0073]-[0076]. Disclosed examples include “aluminum oxide particles,” “organically coated aluminum oxide particles,” and “organic particles.” *Id.*, [0077]. Further, Greenberg emphasizes that the particles must be kept essentially dry, not dissolved in fluid, to work for the intended microdermabrasion treatment:

Of course, great care needs to be taken to ensure that the particle[s] do not become too wet whereupon they will not be able to move freely through the apparatus but will stick to the container and the various tubes.

Id., [0085]. Therefore, a POSITA would have understood that Greenberg’s microdermabrasion treatment solely uses dry particles and lacks the claimed treatment *fluids*.

140. Petitioners do not dispute that Greenberg solely uses dry particles. Petitioners also do not propose any modification of Greenberg to use anything other than dry particles. Rather, Petitioners assert “a POSITA would have understood and found obvious that Greenberg’s ‘particles’ constitute ‘fluid’ within the meaning of the ’287 patent.” Pet., 68.

141. Petitioners’ argument rests entirely upon an interpretation of the claim term “treatment fluid” to encompass a collection of dry particles. To be clear, Petitioners do not assert Greenberg’s dry particles constitute “treatment fluid” under the ordinary meaning of that term. Indeed, Petitioners do not propose *any*

construction of “treatment fluid,” much less one that would encompass a stand-alone collection of dry particles. Petitioners instead attempt to distort a non-limiting list of example substances that may be included in a “treatment material” to suggest it somehow changes “treatment fluid” to cover a stand-alone collection of dry particles. Pet., 69 (citing Ex. 1001, 5:47-54). But Petitioners are incorrect, as explained above, because a “treatment fluid” is not a collection of dry particles.

142. Petitioners also argue that Greenberg discloses the use of “treatment fluid” because it “us[es] an air flow to carry particles through a hand tool.” Pet., 68. Petitioners assert a “POSITA would have understood that the air flow carrying particles is considered to be ‘fluid’ as used in the ’287 patent.” *Id.* But Petitioners cite nothing but Mr. Walbrink’s conclusory testimony. Neither Petitioners nor Mr. Walbrink explains why an “air flow carrying particles” is a “treatment fluid.” In any event, the claims require the treatment fluid to be contained in the containers. When contained in Greenberg’s containers, the dry particles are just sitting together in a pile, not in an air flow carrying particles.

143. Thus, Greenberg does not disclose or make obvious claims 1 or 37.

144. Greenberg does not disclose the claimed invention, at least because its containers store dry particles rather than fluid. Greenberg’s system is a microdermabrasion system, which sprays the dry abrasive particles at the patient’s skin. But, unlike Palmer, Greenberg is at least in the field of microdermabrasion,

which, while different than hydrodermabrasion (the system disclosed and claimed in the '287 patent), is more closely related than the unrelated field of dental irrigation. Thus, if it would have been obvious to combine Karasiuk with the disclosure of multiple treatment containers and container-selection structure to yield the claimed invention, the Examiner would have rejected the claims in view of Karasiuk and Greenberg. The Examiner's finding that the claims are patentable over Karasiuk and Greenberg shows that the claims are likewise patentable over Karasiuk and Palmer.

145. Petitioners rely on Trueba as a secondary reference for Ground 2B. In my opinion, Trueba adds nothing of consequence to Ground 2B because Petitioners do not allege that Trueba discloses the limitations missing from Greenberg (Ground 2B). Rather, Petitioners rely on Trueba as allegedly disclosing a computer interface with a touchscreen and a display for automatically controlling the device. Pet., 90.

2. Greenberg lacks the “treatment material” or “fluid” flowing through components “in fluid communication with” each other of claims 11, 16, 22, and 25-26

146. Claims 11 and 22 recite “treatment material,” and claim 26 recites “fluid,” that flows through various components that are “in fluid communication with” each other. As explained above, the claimed “treatment material” and “fluid” is a substance that easily flows through the components “in fluid communication with” each other, not a collection of dry solid particles. By contrast, Greenberg

discloses a microdermabrasion device that uses a collection of dry solid particles.

Therefore, Greenberg does not disclose or make obvious claims 11, 22, or 26.

147. Dependent claims 16 and 22 further confirm that their claim scope does not encompass dry particles, as explained above. Because Greenberg merely contemplates dry particles, it additionally does not disclose or suggest these dependent claims.

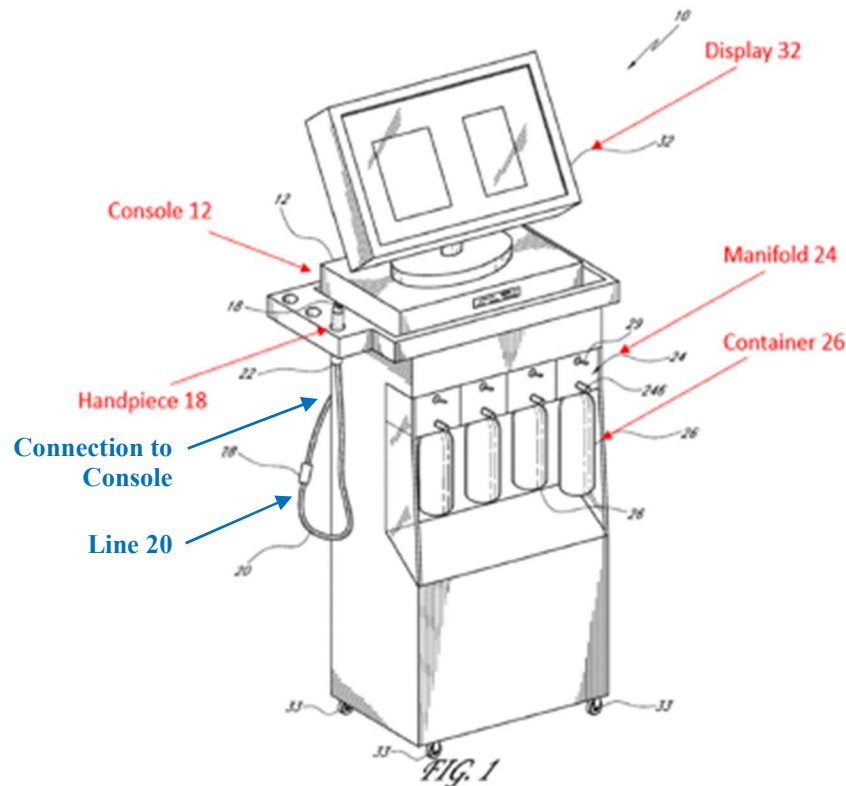
B. Greenberg Does Not Disclose a Handpiece Connected to a Console

148. As I explained above with respect to Grounds 1A and 1B, every claim of the '287 patent requires a handpiece (or handpiece assembly) connected to the console during operation. *See e.g.* Limitations 1.3, 11.3, 22.4, 26.5, and 37.5. For example, Limitation 11.6 recites:

wherein when ... (iii) *the handpiece assembly is connected to the console*, the skin treatment apparatus is configured to selectively draw treatment material from the first container or the second container to the handpiece assembly using, at least in part, a vacuum created along a distal end of the handpiece assembly by the vacuum source.”

Ex. 1001, 22:50-59. Greenberg does not meet these claim limitations.

149. Referring to Figure 1, the '287 patent explains that the “treatment system 10 includes a console 12 and *a handpiece assembly 18 connected to the console 12 via a line 20.*” *Id.*, 5:26-28. The Petition’s annotated Fig. 1 shows this configuration:



Pet., 3 ('287 patent, Fig. 1). The specification explains that “[t]he line 20 can comprise one or more conduits *extending between the console 12 and the handpiece assembly 18.*” Ex. 1001, 5:65-67.

150. Petitioners argue regarding Greenberg’s containers that “[a]s shown in FIG. 1, Greenberg’s supply containers 90, 94, 98 (*first and at least one additional containers; see [1.1]*) are connected to apparatus 10 (*console*).” Pet., 63 (emphasis by Petitioners). Then, Petitioners assert that Greenberg’s handles are also connected to the console because “handles 16, 24 (or handle 102 in FIG. 5) are fluidly connected to various components (e.g., vacuum pump 12, switch 30, valve 54) enclosed in apparatus 10.” *Id.*, 64

151. Greenberg's handle, however, is not connected to apparatus 10. Indeed, Petitioners acknowledge that Greenberg's containers are connected to apparatus 10 and are positioned between the handle and apparatus 10. Thus, Greenberg's handle is connected by tubing to the containers 90, 94, 98—not to apparatus 10. Ex. 1006, Fig. 1, [0053], [0062]. As shown below in Fig. 1, Greenberg does not include a line or conduit connecting the handle to apparatus 10.

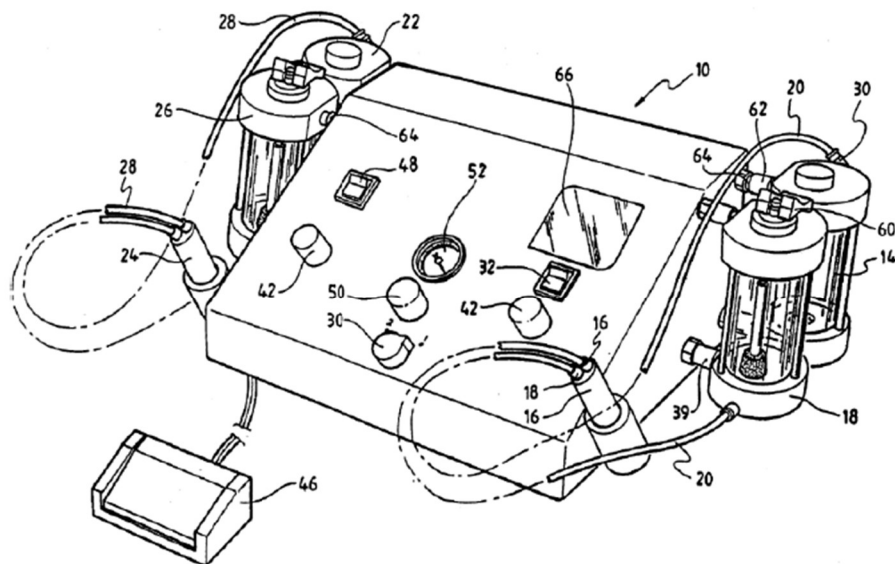


FIG 1

152. Furthermore, storing Greenberg's handle adjacent to apparatus 10, as shown in Fig. 1, does not satisfy this limitation. When Greenberg's handle is resting in the stored position, as shown in Fig. 1, the system is not in use and does not meet the requirements of the claims. For example, claim 1 requires "wherein when the handpiece . . . [is] connected to the console . . . the *system is configured to deliver the first treatment fluid* contained in the first container and the additional treatment

fluid contained in the at least one additional container to the handpiece sequentially.” Ex. 1001, 21:46-57. Claim 11 likewise requires “wherein when . . . the handpiece assembly is connected to the console, the skin treatment apparatus is *configured to selectively draw treatment material from the first container or the second container* to the handpiece assembly using, at least in part, a vacuum created along a distal end of the handpiece assembly by the vacuum source.” *Id.*, 22:50-58. All the independent claims require that the system be configured to deliver treatment material when the handpiece is connected to the console. *Id.*, 23:39-47, 24:34-39, 25:35-26:6. On the other hand, the system in Greenberg is not configured to deliver any material when the handle is in its stored position adjacent to apparatus 10. The system cannot draw or deliver material from the container.

153. Petitioners do not assert that connecting Greenberg’s handpiece to the console would have been obvious. As a result, Greenberg fails to disclose or render obvious the challenged claims.

C. A POSITA Would Not Have Been Motivated to Combine Greenberg’s Different Embodiments

154. In Grounds 2A and 2B, Petitioners must rely on different structures from multiple different embodiments in Greenberg in an attempt to satisfy the claim limitations in the challenged claims. However, Petitioners fail to provide any motivation to combine these different structures, and a POSITA would have lacked

such motivation. Petitioners' combination of these different structures is driven by hindsight alone.

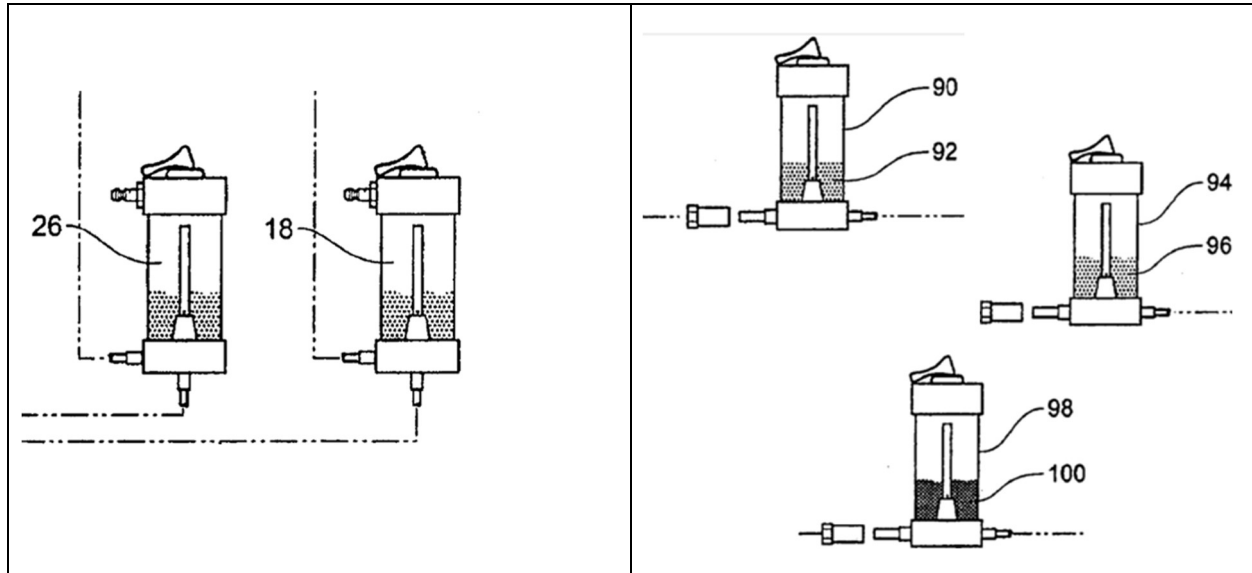
155. For instance, Petitioners assert that Greenberg Fig. 5's three supply containers and two valves would be used instead of Fig. 1's two supply containers (existing in Fig. 1's separate assemblies) and one valve, that Fig. 5's one recovery container would be used instead of Fig. 1's two recovery containers, and that Fig. 5's single handle would be used instead of Fig. 1's two handles. *See* Pet., 57-58. 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.*, 59 (citing Ex. 1003, ¶68).⁵ Petitioners next assert that Fig. 3's "vacuum pump 12" is added to Fig. 5's schematic in an attempt to satisfy limitations related to the vacuum source. *See, e.g.,* Pet., 68-69.

156. 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. *See* Pet., 59-60 (alleging Fig. 5's implementation would have been "similarly applicable" but failing to provide any motivation for modifying). Mr. Walbrink essentially repeats the Petition's

⁵ Regarding the "other structures," Mr. Walbrink describes just Fig. 1's "tube 20" for use in Fig. 5. Ex. 1003, ¶68.

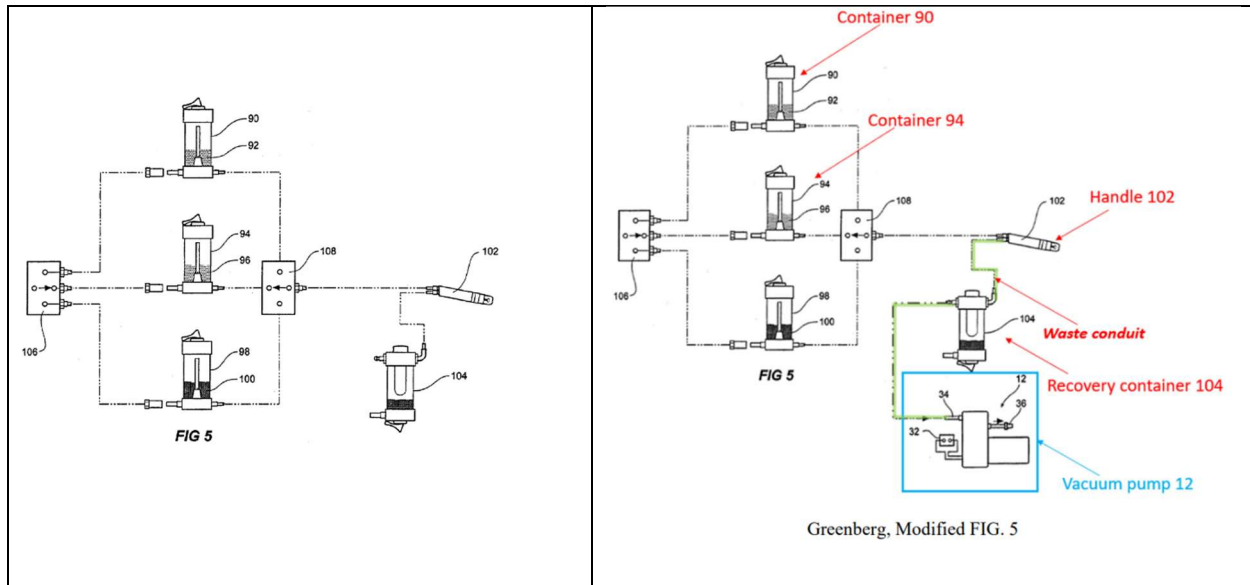
description and also fails to provide any motivation for the combination of different structures. *See* Ex. 1003, ¶68.

157. Greenberg even indicates that these structures in the Figs. 1-4 embodiments are not compatible with the Fig. 5 embodiment. For instance, 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. But in the Fig. 5 embodiment, Greenberg uses different reference numbers for Fig. 5’s supply containers, recovery container, and handle. *Compare, e.g., id.*, Figs. 1-4 (reference numbers 18, 26 for supply containers) *with* Fig. 5 (reference numbers 90, 94, 98 for supply containers). Furthermore, Greenberg indicates in Fig. 5 that those supply containers are structurally different than, e.g., the Fig. 2 supply containers, having different outlet configurations:



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

158. 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 the attempt to address the “vacuum source” recited in the independent claims, Petitioners point to Fig. 3’s “vacuum pump 12.” Pet., 68-69. Petitioners include an image in the Petition that literally concatenates Fig. 3’s vacuum pump 12 onto the Fig. 5 schematic, which in its original does not include a vacuum.



Ex. 1006, Fig. 5; Pet. 70.

159. Petitioners, however, never address whether a POSITA would have even been motivated to modify Fig. 5 in this manner or how, after Petitioners' proposed modification, the different supply containers of Fig. 5 will work with a vacuum source. *See* Pet., 68-69. Petitioners have presented no evidence that a POSITA would have been motivated to combine these different embodiments even if a POSITA could combine these different embodiments.

160. A POSITA would not have been motivated to add a vacuum source to Greenberg's Fig. 5 embodiment. Greenberg's Fig. 5 embodiment lacks any type of pneumatic source, whether a vacuum or a compressor. A POSITA in 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. As 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]. That is, Greenberg indicates that air pressure to propel the abrasive particles is supplied to the system from a compressor upstream of valve 106 to supply air to the respective supply container and thereby aerate the particles in the container and drive the particles through valve 108 to handle 102.

161. In Ground 2A, Petitioners and Mr. Walbrink have not shown that a POSITA would have been motivated to combine Greenberg’s different embodiments to arrive at the claimed invention. The additional prior art Petitioners rely on in Ground 2B cannot remedy the deficiencies in Greenberg. Petitioners add only Trueba to the combination in Ground 2B, but this combination fails to address any of the deficiencies in Greenberg in Ground 2A. Moreover, adding Trueba’s mucosal inhaler that employs Hewlett Packard inkjet technology will only make the already complicated combination of different Greenberg embodiments worse. Thus, the Petitioners have failed to show that the challenged claims would have been obvious in view of Ground 2A and 2B.