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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

v.

HYDRAFACIAL LLC,

Patent Owner.

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

PATENT OWNER PRELIMINARY RESPONSE

[REDACTED - PUBLIC VERSION]

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I. INTRODUCTION

HydraFacial pioneered the field of hydrodermabrasion, revolutionizing skin treatment by introducing systems that deliver multiple fluid-based therapies in a single, customizable procedure. The '477 patent protects the core innovations underlying these systems—innovations that created an entirely new category of skincare, generated [REDACTED] in sales, and established HydraFacial as the leader in non-invasive skin resurfacing.

The Board should decline institution. Petitioners have challenged the '477 patent using the same prior art that was fully litigated—and rejected—before the ITC in *Certain Hydrodermabrasion Systems and Components Thereof*, Inv. No. 337-TA-1408. The ITC investigation addressed the related U.S. Patent No. 11,865,287 (“the '287 patent”), which shares the same specification as the '477 patent and is terminally disclaimed with respect to it. Following a five-day trial with extensive expert testimony, the Administrative Law Judge (“ALJ”) upheld the validity of the '287 patent and expressly rejected the same prior art on which Petitioners now rely.

The ALJ found the cited references concern fundamentally different technologies—such as dry-particle microdermabrasion (Greenberg), mucosal inhalers (Trueba), single-reservoir skin treatments (Karasiuk), and dental irrigation (Palmer)—and that any attempt to combine them involves “classic impermissible

hindsight.” Ex.2161, 152. The ITC’s findings further reinforce the patentability of the ’477 claims over the same art.

The Petition merely repackages the same unsuccessful theories to reconstruct the invention through hindsight. In Grounds 1A-1D, Petitioners combine Karasiuk’s single-reservoir, high-viscosity skin treatment device with Palmer’s one-way “pulsed-jet” dental irrigation system—two fundamentally different systems designed for distinct environments and fluid dynamics. The resulting hybrid is inoperable and lacks the claimed manifold system, even under Petitioners’ own definition. In Grounds 2A-2B, Petitioners turn to Greenberg, which the ITC has already found inapposite to HydraFacial’s claimed technology because it concerns dry, abrasive microdermabrasion rather than the liquid “treatment materials” recited in the claims. Like the other references, Greenberg also lacks the claimed manifold system.

HydraFacial’s patented hydrodermabrasion systems have achieved remarkable commercial success, maintained dominant market share, and have been widely copied by competitors, including Petitioners. This constitutes strong objective evidence, recognized by the Federal Circuit as among the most probative, which independently confirms the nonobviousness of the ’477 patent claims at the time of the invention. Taken together with the Petition’s meritless prior-art challenge and the ITC’s corroborating findings, these objective indicia confirm the

patentability of the challenged claims. Petitioners have not met their burden under Section 314(a), and institution should be denied.

II. THE ITC UPHELD THE '287 PATENT'S VALIDITY

The '287 patent is in the same family as, and terminally disclaimed to, the '477 patent. *See* IPR2025-00145, Ex.1002, 191-195. HydraFacial asserted the '287 patent against Eunsung Global Corp. and its exclusive distributor, Cartessa Aesthetics, LLC ("Cartessa"), in *Certain Hydrodermabrasion Systems and Components Thereof*, Inv. No. 337-TA-1408 ("*Cartessa ITC*"). Ex.2068. After a five-day trial in April 2025, the ALJ issued an Initial Determination in August 2025 (Ex.2161), finding that the asserted claims were infringed and upholding the validity of the '287 patent. The ALJ rejected the invalidity challenge based on the same prior art references relied upon here—including Greenberg, Karasiuk,¹ Palmer, and Trueba—and further determined that the commercial success of HydraFacial's systems provided independent and compelling evidence of nonobviousness. Ex.2161, 99-161, 174-84.

¹ In *Cartessa ITC*, the asserted Karasiuk reference was U.S. Patent No. 6,695,853 (Ex.2168, "Karasiuk-853"), which is the parent of the Karasiuk continuation-in-part publication cited by Petitioners in this IPR (Ex.1004).

III. BACKGROUND AND PATENTED TECHNOLOGY

A. HydraFacial and Hydrodermabrasion

HydraFacial pioneered the field of hydrodermabrasion and is a worldwide leader in the design, development, manufacture and sale of high-quality hydrodermabrasion systems. These systems rejuvenate skin by applying different liquid solutions to the skin to cleanse and exfoliate the skin surface, extract debris from pores, and thoroughly hydrate and moisturize the skin. HydraFacial markets and sells these 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 solutions and the cleaning solution.



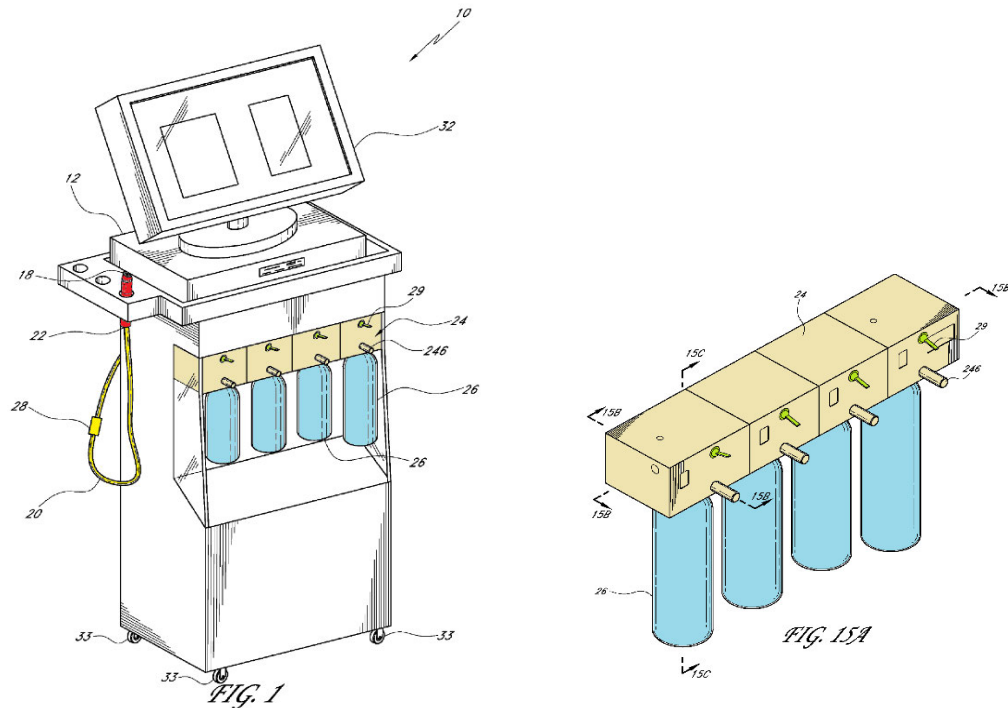
The hydrodermabrasion industry owes its origin to HydraFacial and its patented technology. HydraFacial's revolutionary hydrodermabrasion systems, including the Syndeo above, are protected by the '477 patent. The disclosure of the '477 patent dates back to 2005 and is the original disclosure describing HydraFacial's hydrodermabrasion systems that created the industry.

B. The Patented Technology

The '477 patent discloses a skin treatment system that applies treatment liquids from multiple containers sequentially or simultaneously to the patient's skin. Ex.1001, 6:19-22; *id.*, 13:14-15. Unlike prior art microdermabrasion systems that

are often painful and will dry out and often damage the skin (*id.*, 1:41-50, 2:9-15), the systems disclosed in the '477 patent exfoliate dead skin cells and extract impurities by applying a vacuum “while simultaneously bathing the healthy underlying skin with active treatment material.” *Id.*, 7:52-56. These treatment materials “can facilitate cleansing, exfoliating, hydrating, and/or provide residual antioxidant protection.” *Id.*, 7:56-58. The claims of the '477 patent are directed to skin treatment systems that have multiple containers containing the treatment materials and involve removing waste from the skin surface via a waste conduit while drawing treatment materials from the first container or second container to the working end of a handpiece assembly via the supply conduit. *See, e.g.*, claim 1.

The treatment system applies treatment liquids to a person's skin while simultaneously suctioning spent treatment fluid and debris away from the skin and into a waste container. Ex.1001, 5:54-60, 7:43-51. The user can select a desired treatment medium from multiple treatment-fluid containers (shown in blue below). *Id.*, 6:13-22, 15:53-55, 17:9-21.



Id., Figs. 1 (annotated), 15A (annotated). The '477 patent describes the same treatment materials used in the Syndeo and other HydraFacial commercial products: “active-4™” as a cleansing and exfoliating serum (*id.*, 15:53-65); “Beta-HD™” as a salicylic acid extraction serum (*id.*, 15:65-16:6); and “Antiox-6™” as an antioxidant hydration serum (*id.*, 16:6-15).

HydraFacial’s patented system can also include a manifold system (shown in beige above). The manifold system can connect to the treatment material containers of the system and, when there is at least one container connected to the system, the container is in fluid communication with the handpiece assembly (shown in red above) through a supply conduit (shown in yellow above). *Id.*, 2:23-28, 3:50-52, 5:19-22, 6:14-16, 17:9-21, 17:65-19:3. The system also contains a vacuum source

which, when the user contacts the working end of the handpiece assembly against the skin, creates an area of negative pressure inside the tip. *Id.*, 10:63-11:2. That negative pressure pulls the patient's skin against the working end of the handpiece assembly. *Id.*, 10:63-11:5. The negative pressure also draws treatment material from the selected container while simultaneously suctioning waste and spent treatment fluid into a waste container. *Id.*, 7:52-65, 10:63-11:9. The multiple treatment material containers allow the physician or esthetician using the device to selectively draw treatment material from the containers and thereby provide a customized, multi-step treatment for each patient. *Id.*, 6:16-29, 16:26-51.

C. Level of Ordinary Skill in the Art

As explained by Mr. Leinsing, a POSITA for the '477 patent would have a degree in science or engineering plus a minimum of three years of experience in the medical device industry. Ex.2001, ¶22. Alternatively, a product designer could have an additional two years of experience in the industry in lieu of a formal science or engineering degree. *Id.* 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 skin. *Id.* This definition of a POSITA appropriately takes into consideration both engineering knowledge important for understanding mechanical aspects of the device and the skin treatment implications of the device.

Petitioners' definition of a POSITA, which does not adequately account for the medical and skin treatment implications of the system, affects both Petitioners' and Mr. Walbrink's analysis of the claims in view of the prior art. When the differences between the prior art and the claimed invention are assessed in purely mechanical terms, it can lead to hindsight bias. For example, Mr. Walbrink has adopted Mr. Simon's expert declaration as his own (*see* Ex.1034, ¶19), but Mr. Walbrink fails to appreciate that Mr. Simon did not account for the differences between HydraFacial's patented technology and the prior art technology Mr. Simon holds a patent on. *See* Ex.2014 (Simon patent directed to dry-particle microdermabrasion). As explained below, this hindsight bias invades Walbrink's adopted opinions as he relies on Greenberg's old-style dry abrasive microdermabrasion system and attempts to combine Palmer's dental irrigation technology with the Karasiuk's single-reservoir skin treatment system.

Nevertheless, despite these important differences in the definition of a POSITA, HydraFacial's expert has assessed obviousness under both HydraFacial's and Petitioners' definitions and determined the claims would not have been obvious under either definition. Ex.2001, ¶¶21-25.

IV. CLAIM CONSTRUCTION

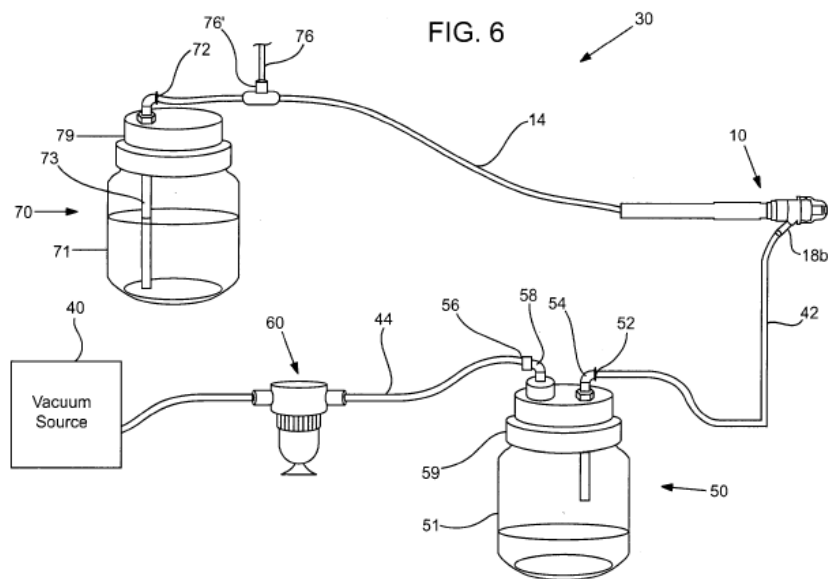
Petitioners assert that "[n]o formal claim constructions are necessary." *See* Pet., 2. HydraFacial agrees no formal constructions are necessary, except to address

Petitioners' implicit constructions in two instances. First, HydraFacial addresses the ordinary meaning of "manifold"² as understood by both parties. Second, HydraFacial addresses Petitioners' implicit and incorrect construction of "treatment material." Ex.2001, ¶26.

V. THE CLAIMS OF THE '477 PATENT ARE PATENTABLE OVER THE PRIOR ART

A. Karasiuk

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

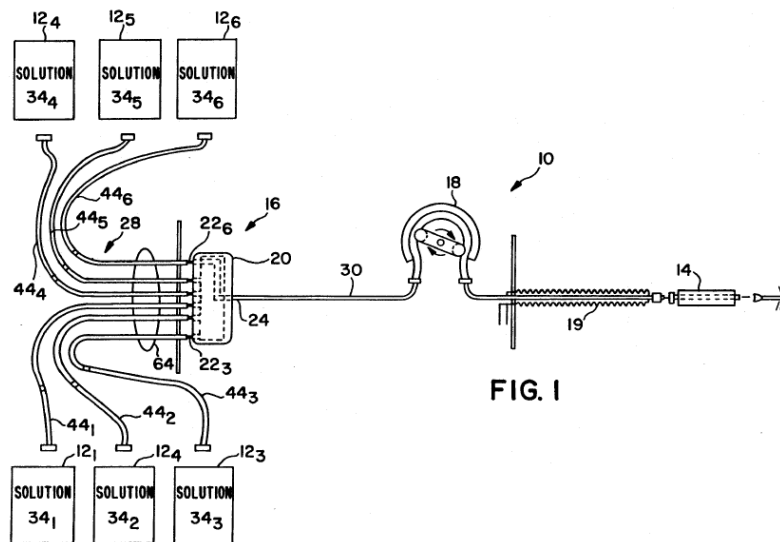


² Although the claims recite a "manifold system," Petitioners' proposed definition is in relation to a "manifold."

Ex.1004, Fig. 6, [0020]. Karasiuk indisputably lacks a manifold system in communication with a first container and an at least a second container as recited in independent claims 1, 9, and 15. Nothing in Karasiuk suggests separately storing and applying different treatment materials in a single treatment. At most, Karasiuk lists different solutions, suspensions, or compounds that can be contained “alone or in combination” in Karasiuk’s single reservoir 70. *Id.*, [0061]; Ex.2001, ¶¶33, 34.

B. Palmer

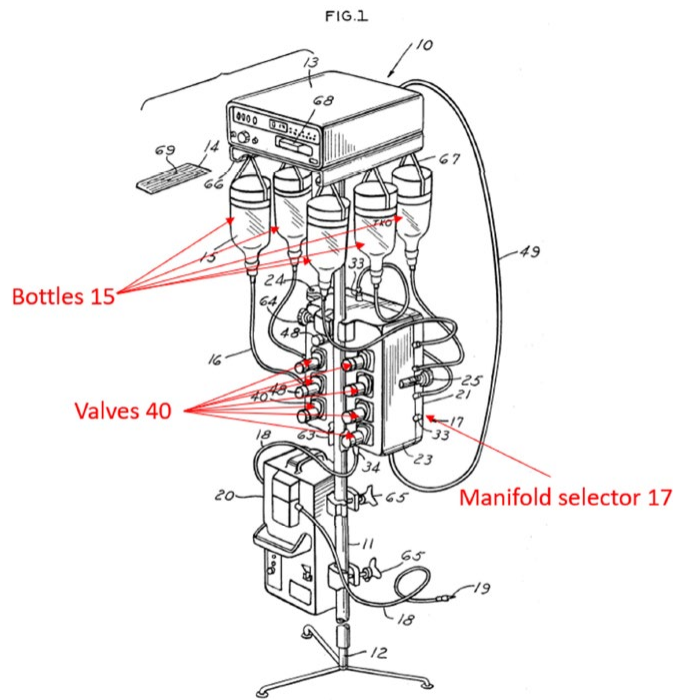
Palmer is an irrigation system used in periodontal procedures. Ex.1005, 1:10-15. Accordingly, Palmer delivers “pulsed jets” of solution to a patient’s mouth at a constant pressure and volumetric flow rate. *Id.*, 2:52-56, 11:17-23 (25 psi and 22-25 mL/minute). Palmer uses a peristaltic pump 18 located upstream of handpiece 14 to generate the pulsed jets, as shown in Fig. 1. Ex.2001, ¶35.



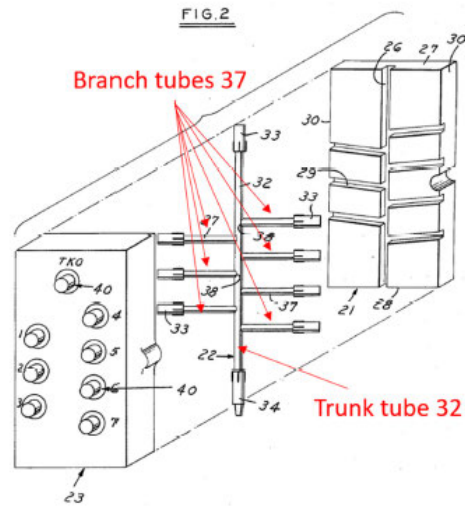
Ex.1005, Fig. 1. Unlike a skin treatment system, Palmer is a one-way irrigation system that lacks any mechanism to draw the spent solution from the patient's mouth and back through the handpiece. Indeed, Palmer uses the peristaltic pump “as a natural check valve since it cannot aspirate solution back into the cannula” of the handpiece. *Id.*, 3:30-33; Ex.2001, ¶¶35-36.

C. Wunsch

Wunsch describes a system for sequentially dispensing multiple intravenous (IV) solutions from multiple solution sources through a single catheter. Ex.1020, 5:18-22. Each solution source is connected to a distinct branch (*e.g.*, branch tubes 37) of a manifold (*e.g.*, combination of trunk tube 32 and branch tubes 37), with flow through each branch controlled by a valve selector that actuates valves mounted on a manifold plate. *Id.*, 7:49-52. These valves are individually actuated by electronically operable motors or solenoids. *Id.*, 6-18-26; Ex.2001, ¶42.



Wunsch, FIG. 1 (annotated)



Wunsch, FIG. 2 (annotated)

Pet., 49, 51.

The “manifold system” (*e.g.*, combination of trunk tube 32 and branch tubes 37) from Wunsch cannot, independently, control the flow of treatment of material. *See* Ex.1020, 4:1-10, 7:17-56; Pet., 50 (“In operation, by activating an individual valve 40, the user can selectively connect a chosen bottle 15 to the trunk tube 32 for delivery.”). The “manifold” of Wunsch (*i.e.*, the trunk tube 32 and branch tubes 37) would result in an open system with uncontrolled, free-flowing liquid from each solution source. Ex.2001, ¶43.

Wunsch’s volumetric infusion pump meters the dispensed quantity of each solution. Ex.1020, 6:7-13. The sequence and timing of solution delivery is governed by a sequencer-timer, which automatically and successively actuates each valve in

accordance with a predetermined program (*e.g.*, stored on a program card). *Id.*, 5:25-35, 51-55; Ex.2001, ¶44.

D. Greenberg

Greenberg discloses a microdermabrasion machine that uses dry abrasive particles to abrade the skin. *See* Ex.1006 at Abstract. Greenberg is focused on “using abrasive particles of different sizes and/or type.” *Id.*, [0002]. For example, the embodiment in Figs. 1-2, includes two separate and distinct assemblies on either side of the machine, each with its own recovery container, supply container, and handle to separately drive particles of different sizes or type. *Id.*, [0049]; Ex.2001, ¶¶45-48.

Greenberg includes different embodiments of the microdermabrasion machine. The embodiment in Fig. 3 includes two assemblies, each with a supply container 18, 26 and recovery container 14, 22 and a handle 16, 24. Ex.1006, [0065]. However, unlike the version in Figs. 1-2, 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.*; Ex.2001, ¶49.

The embodiment 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. Ex.1006, [0067]. It has a valve 30 that connects the supply containers 18, 26 to the different handpieces 16, 24. Ex.2001, ¶50.

The embodiment in Fig. 5 includes three containers 90, 94, 98, one recovery container 104, and one handpiece 102. Ex.1006, [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 a vacuum source downstream of the recovery container. Ex.2001, ¶51. Greenberg discloses another version in Fig. 6 that includes one supply container and one recovery container. *Id.*, ¶52. All versions disclosed by Greenberg employ riser tubes that are generally not compatible with liquid suctioning. Ex.1006, Figs. 1-6; Ex.2001, ¶52.

E. Grounds 1A-1D: Palmer Is Not Analogous Art

Consistent with the ITC’s findings, the Board should reject Petitioners’ challenge under Grounds 1A-1D because Palmer is not analogous art to the ’477 patent. Ex.2161, 150-155.

First, Palmer is not in the same field of endeavor as the ’477 patent, which is directed to skin treatment devices. Ex.1001, Abstract (“An apparatus for treating skin....The handpiece assembly is configured to treat skin”), 1:23-25 (“The

invention relates in general to the field of skin treatment, and more specifically to apparatuses and methods for treating a person's skin."), 21:15 (cl. 1) ("A skin treatment system comprising....").

Palmer, in contrast, is directed to a dental irrigation device that sprays a solution directly into the patient's mouth, lacks a vacuum source, and does not provide fluid recovery from the patient's mouth. Ex.1005, 1:10- 17 ("The advantages of irrigation as a viable periodontal treatment are well documented."), 11:44-46 (cl. 11) ("Periodontal irrigating system for delivering one of a plurality of liquid irrigating solutions to a treatment site in an oral cavity"). The ALJ in *Cartessa ITC* reached the same conclusion with respect to Palmer and the related '287 patent. Ex.2161, 150-151.

Next, Palmer is not reasonably pertinent to the particular problem that the inventors of the '477 patent sought to address. The '477 patent identifies those problems as the pain associated with dermabrasion of the skin, the mess created during traditional microdermabrasion, the redness that results from the process, and the lengthy recovery times required for the skin to regrow and heal. Ex.1001, 1:41-2:15; Ex.2161, 151-152.

In contrast, Palmer states, e.g., that the object of its invention is "to provide ***new and improved irrigation systems*** and methods for delivering one of a selected one or more of multiple liquid solutions to a treatment site" and to do so "at a

substantially uniform delivery pressure and volumetric flow rate.” Ex.1005, 2:48-56.³ Palmer’s stated objectives—relating to fluid pressure control and irrigation delivery—are not pertinent to the skin-treatment problems addressed by the ’477 patent, including the pain, mess, redness, and extended recovery associated with earlier microdermabrasion techniques. The ALJ in *Cartessa ITC* reached the same conclusion with respect to the ’287 patent, finding that Palmer is not analogous art. Ex.2161, 151-155. The analogous art requirement is “meant to defend against hindsight,” such as this. *LKQ Corp. v. GM Glob. Tech. Operations LLC*, 102 F.4th 1280, 1297 (Fed. Cir. 2024) (en banc).

F. Grounds 1A-1D: Neither General Knowledge nor Karasiuk’s Disclosure Provides a Motivation to Modify Karasiuk

Petitioners allege a motivation to modify Karasiuk 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.***” Pet., 10. But 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-

³ Emphasis added by HydraFacial throughout unless noted otherwise.

container system to add more containers from Palmer or add a “manifold.” Ex.2001, ¶106.

1. “General Knowledge” of Microdermabrasion Was Not a Motivation

The Petition provides no explanation of the “general knowledge” that supposedly motivates a POSITA to modify Karasiuk. Petitioners punt this task to their expert witness. Pet., 9 (citing Ex.1003, ¶¶85-95). But Walbrink’s supposed “general knowledge” motivation is deficient for several reasons.

First, Walbrink contends that “multiple treatment solutions are desirable *during microdermabrasion.*” Ex.1003, ¶86 (citing Burgess (Ex.1013) and Lee (Ex.1016)). But Walbrink’s cited evidence directly contradicts his contention. For example, Burgess states that sunscreen is applied *after* completing the old-style microdermabrasion procedure—not during. Ex.1013, 86 (“*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.”) This is because old-style microdermabrasion involves the use of “fine, sharp crystals” to sandblast the skin. Ex.1013, 84. It makes no sense to apply moisturizer during microdermabrasion while the skin is being sandblasted with fine, sharp crystals. Walbrink himself agrees, noting that moisturizer is applied “when microdermabrasion *is completed.*” Ex.1003, ¶86; Ex.2001, ¶110. Thus, no treatment

solution is applied **during** microdermabrasion, let alone multiple treatment solutions, as Walbrink alleges. Ex.2001, ¶110.

Next, Walbrink cites to Lee as “general knowledge,” but Walbrink misapprehends the reference when he alleges “Lee discloses delivering vitamin C during microdermabrasion.” Ex.1003, ¶100 (citing Ex.1016, 1). Like Burgess, 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); Ex.2001, ¶111. In no way does Lee provide any motivation to use multiple types of treatment solutions during microdermabrasion as Walbrink alleges. Ex.2001, ¶111.

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., 11. Here, Petitioners provide a citation to Walbrink and a string citation (without pin cites) to several different, unrelated references that purportedly show the general knowledge art, with no substantive explanation. *Id.* The references include Hewlett Packard’s jet dispenser system (Trueba (Ex.1008)) and multiple dental irrigation systems (Palmer

(Ex.1005), Armstrong (Ex.1011), and Pond (Ex.1007)). This string citation, without any substantive explanation, does not satisfy Petitioners' obligation to explain why a person of ordinary skill in the art would have modified Karasiuk based on the purported general knowledge in the art. Ex.2001, ¶112.

Walbrink's cited testimony is conclusory. Ex.1003, ¶¶87-91; Ex.2001, ¶112. He gives a vanilla description of the references and fails to explain how incorporating the structure from any of the disparate devices would, as he claims, "improve the flexibility and functionality offered by Karasiuk's system." Ex.1003, ¶87. That these references contain "multiple containers" and were "well-known and part of a POSITA's general knowledge," as Walbrink avers, does not, by itself, apprise a POSITA with any reason to modify Karasiuk. *Id.*; Ex.2001, ¶113. The mere fact that multiple containers were used in some contexts would not have suggested to a POSITA that using multiple containers would have improved Karasiuk's single-container design. Ex.2001, ¶¶112, 113. And merely alleging generic advantages such as flexibility and functionality is insufficient absent specific evidence why a POSITA would have modified Karasiuk to yield the claimed

invention. *ActiveVideo Networks, Inc. v. Verizon Commc'ns., Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012).⁴

For these reasons, Petitioners have failed to show that “general knowledge” provides a motivation to modify Karasiuk to include multiple containers with multiple types of treatment solutions. *Cisco Sys., Inc. v. Video Sols. PTE. Ltd.*, IPR2024-00922, Paper 7 at 14 (PTAB Nov. 12, 2024) (“Put simply, we are not persuaded by Petitioner’s arguments regarding the background knowledge art because those arguments are not sufficiently explained.”); Ex.2001, ¶113.

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

Petitioners cannot cite to any disclosure in Karasiuk of using multiple containers or even multiple types of treatment solutions. Further, Petitioners fail to provide any evidence a POSITA would have considered the lack of multiple containers in Karasiuk’s system as a problem. As the ITC held, “there is no evidence that a person of ordinary skill in the art would have considered the lack of multiple

⁴ Petitioners also make a half-hearted “mere duplication” argument. Pet., 11 (citing *In re Harza*, 274 F.2d 669 (CCPA 1960)). Even if it were articulated, the argument is inapposite because it fails to account for additional claimed structure and function, such as the claimed manifold system.

containers in the system depicted in Figure 6 of Karasiuk as a problem.” Ex.2161, 157.

The only disclosure Petitioners cite to support this contention is: (1) Karasiuk’s different compounds used in a ***single reservoir*** 70 (e.g., “lotions/vitamins or other fluids”); and (2) Karasiuk’s boilerplate that “various [undescribed] changes” may be made “without departing from the true spirit and scope of the invention.” Pet., 10-11 (quoting Ex.1004, [0024], [0047], [0061], [0070]). Walbrink cites and quotes these same passages without any explanation. Ex.1003, ¶¶85, 87; Ex.2001, ¶114

Rather than finding motivation to use multiple containers, a POSITA would have recognized Karasiuk’s simplicity in combining various constituents in a ***single reservoir*** 70 to achieve the benefits of each individual constituent. Ex.2001, ¶115. 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. *Id.*

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. This argument is meritless. Ex.2001, ¶116. 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.

Ex.2001, ¶117.

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

Petitioners assert that in view of “general knowledge” and “Karasiuk’s disclosure,” a POSITA “would have investigated other references such as Palmer to achieve benefits offered by multiple treatment solutions.” Pet., 11-12. 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. Ex.2001, ¶118. As the ALJ recognized in *Cartessa ITC*, reliance on Palmer for this obviousness challenge constitutes “*classic impermissible hindsight.*” Ex.2161, 152 (“Because Cartessa’s reliance on Palmer for its obviousness argument is classic impermissible hindsight, Cartessa’s obviousness argument fails as a matter of law.”).

It is no surprise then that the alleged “benefits” Petitioners have selected from Palmer are rooted in the needs of periodontal irrigation systems at the time, not any then-known skin treatment system. Petitioners’ attempt to shoehorn them into Karasiuk’s skin treatment system can only be explained with impermissible hindsight. *Id.*, ¶108.

The **first and second alleged benefits** are “allow[ing] easy selection among multiple treatment solutions” and “enabl[ing] sequential delivery of different

treatment solutions.” Pet., 11-12. However, both benefits are premised on Palmer’s described need for multiple irrigating solutions delivered sequentially in a periodontal procedure—i.e., hydrogen peroxide for “removal of loose organic debris,” zinc chloride for “reduc[ing] inflammation,” sodium fluoride for “desensitization of tooth structure,” and stannous fluoride and chlorhexidine digluconate for “reduction of bacterial concentration.” Ex.1005, 1:33-43; *id.*, 5:52-64. Palmer’s motivation was, as Petitioners agree, the drawback in “conventional irrigation arrangements” that did not provide “the opportunity of easy selection among several irrigant solutions.” Petition, 11 (quoting Ex.1005, 1:30-53); Ex.2001, ¶120.

Palmer’s additional disclosure further informs a POSITA the sequential delivery was actually unique to periodontal irrigation systems, which involved color coding the solutions and use of “flavor coordinated” solutions. Ex.1005, 3:42-48. Using “substantially the same predetermined flavor” allows a patient to be “treated with two or more solutions during the procedure, *one after the other*, without being subjected to the discomfort which would normally occur when a person tastes two or more *diverse flavors, one immediately after the other.*” Ex.1005, 6:42-51 (emphasis added). Petitioners erroneously cite this passage in alleging POSITA would have applied Palmer’s teachings to Karasiuk’s skin treatment system, but the

sequential delivery is clearly meant for periodontal irrigation systems. Pet., 12. Ex.2001, ¶121.

Dental clinicians would have recognized the lack of easy selection among irrigant solutions to be a problem for dental-irrigation devices because delivering multiple dental-irrigation solutions together in a single step would necessarily dilute and destroy the efficacy of many such solutions. Ex.2001, ¶122. By contrast, Petitioners do not identify any such drawback with Karasiuk's skin treatment system; rather, a POSITA would have expected Karasiuk's delivery of a mixture of treatment fluids in a single step to achieve the efficacy of each of individual fluids. Therefore, Petitioners have not shown that clinicians would have recognized any problem with Karasiuk's single-container design in need of a solution. *Id.*, ¶111.

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

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

Ex.1005, 1:47-53 (cited by Pet., 11). Palmer's opinion that cleaning and refilling a dental-irrigation tank is a time-consuming, costly, and messy procedure is irrelevant to Karasiuk's skin treatment procedure. Ex.2001, ¶122. Neither Petitioners nor 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. *Id.*, ¶111.

The **third alleged benefit** is "minimiz[ing] refilling downtime because when a particular container runs out mid-operation, the combined system can quickly switch to a second container to keep the supply flowing." Pet., 12. However, Petitioners present no evidence a POSITA would have considered Karasiuk's reservoir to be too small to contain sufficient treatment fluid for its purpose. And if the size of Karasiuk's reservoir were a concern, Petitioners present no evidence a POSITA would have been motivated to add complicated valves and tubing simply to allow a clinician to switch to an extra container of the same treatment fluid. Indeed, 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. Ex.2001, ¶123. 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.

Id., ¶112.

The **fourth alleged benefit** is “Palmer’s modular design to provide added flexibility, organization, and portability.” Pet., 12. But this supposed benefit is irrelevant to Petitioners’ proposed change from Karasiuk’s single-container design to a multi-container design. Rather, as Petitioners recognize, it relates to the desirability of container placement in a variety of *locations*, such as on a countertop, on a mobile cart, in a cabinet, or underneath a counter. Pet., 12-13; *see also* Ex.2001, ¶124.

In sum, Petitioners’ citation to Palmer’s benefits for periodontal irrigation is premised entirely on a hindsight reconstruction of the claimed invention. Petitioners present no evidence a POSITA would have appreciated any of these benefits in the field of skin treatment before the priority date of the ’477 patent. While those in the field now understand the benefits of, e.g., sequential delivery in view of the teachings of the ’477 patent and the success of HydraFacial’s commercial embodiments of the ’477 patent, it would be legally improper to assume, without evidence, that a POSITA would have appreciated those benefits at the time of the invention. Ex.2001, ¶125.

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

“[C]ombinations that change the ‘basic principles under which the [prior art] was designed to operate,’ or that render the prior art ‘inoperable for its intended purpose,’ may fail to support a conclusion of obviousness.” *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F. App’x 755, 757–758 (Fed. Cir. 2015) (non-precedential) (quoting *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959); *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984)).

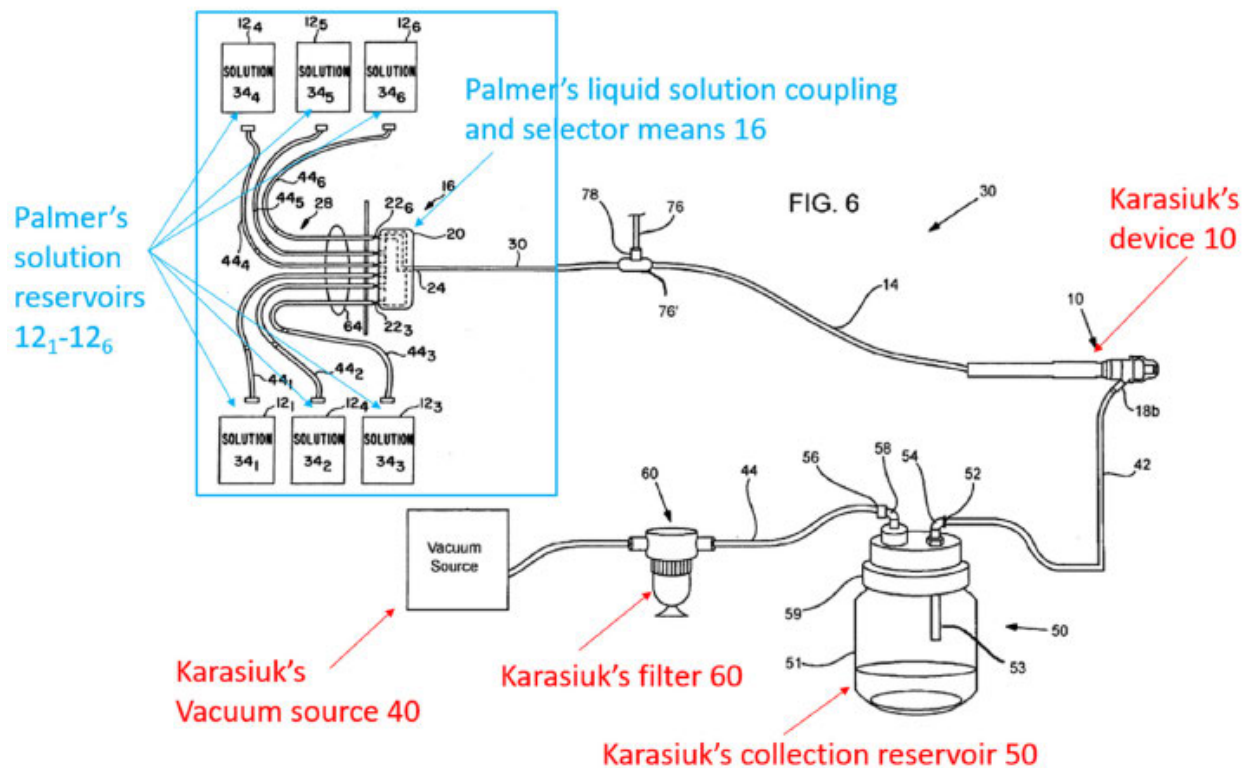
Grounds 1A-1D in the Petition rely on the combination of Karasiuk and Palmer. Pet., 1. As explained below, Petitioners’ combination of these two systems would fundamentally alter their operation in multiple ways and make Karasiuk’s device inoperable for its intended purpose. Ex.2001, ¶57; *see also id.*, ¶37. The Karasiuk system as modified with Palmer cannot deliver treatment solutions to the handpiece. *Id.* A POSITA would have had no motivation to construct a device that does not work from these unrelated pieces of prior art. *Id.*

These flaws in the combined Karasiuk-Palmer system are fatal to all proposed grounds of unpatentability under Ground 1A-1D. *See, e.g., Samsung Electronics Co. Ltd. v. Neonode Smartphone LLC*, IPR2021-00144, Paper 24 at 13-14 (citing *Plas-Pak* and denying institution where proposed combination would change reference’s principle of operation and render it inoperable); *R.J. Reynolds Vapor Co.*

v. Fontem Holdings I B.V., IPR2018-00629, Paper 10 at 19-20 (citing *In re Gordon* and denying institution where proposed modification would render prior art unsatisfactory for its intended purpose such that “there is no suggestion or motivation to make the proposed modification.”); Ex.2001, ¶57.

1. Karasiuk-Palmer’s Vacuum Source Draws Only Air through the Breather Line and Never Draws Material from the Reservoirs

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., 9. That is, Petitioners remove Palmer’s peristaltic pump from Palmer’s system and instead relies on Karasiuk’s vacuum source 40 downstream of the handpiece to act as the vacuum source in the combined device. Ex.2001, ¶58. Petitioners depict this combination as a literal concatenation of Palmer’s Fig. 1 and Karasiuk’s Fig. 6, calling it “Karasiuk, Modified FIG. 6”.



Karasiuk, Modified FIG. 6

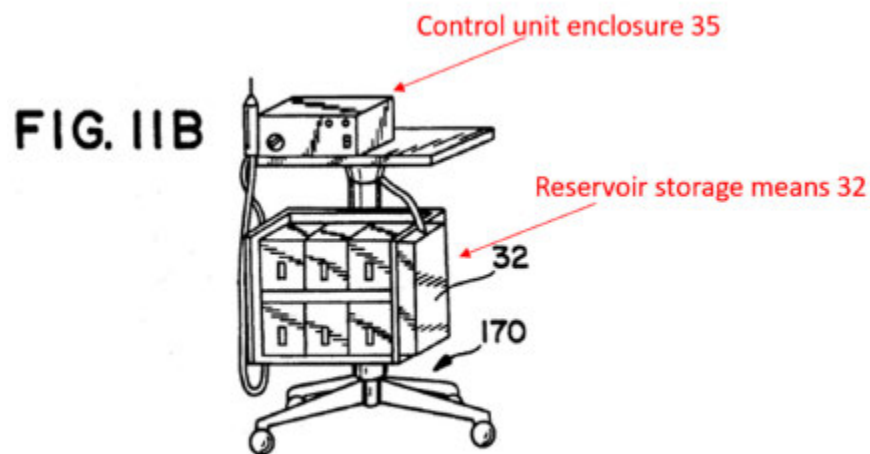
Pet., 9, 17.

Petitioners arrange the mash-up device such that “Karasiuk’s tube 14 (e.g., *upstream of breather line 76*) would replace, or be connected to, Palmer’s second tubing means 30 to achieve benefits resulting from selection of different treatment solutions.” Pet., 9 (emphasis added), 24, 26. Thus, Petitioners have positioned Karasiuk’s breather line 76 upstream of Karasiuk’s device 10 (the handpiece) and downstream of both Palmer’s “liquid solution coupling and selector means 16” and Palmer’s solution reservoirs 12₁ - 12₆. *Id.* Petitioners repeatedly contend that this

arrangement “achieve[s] benefits resulting from selection of different treatment solutions.” Pet., 9, 24, 26; Ex.2001, ¶59.

Karasiuk explains that the breather line 76 “includes an adjustable valve 78 or other means for varying an amount of air that is allowed into tube 14.” Ex.1004, 7:19-23. The feature “allows the amount vacuum to be adjusted for a given fluid.” *Id.*, 7:23-24; Ex.2001, ¶60.

Petitioners’ Karasiuk-Palmer mash-up combination also involves adoption of Palmer’s “mobile cart 170” for allegedly providing “increased portability and/or organization.” Pet., 7-8. 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, located underneath the system components in the “control unit enclosure 35,” which are on the shelf above:



Palmer, FIG. 11B

Pet., 14; *see also* Ex.2001, ¶61.

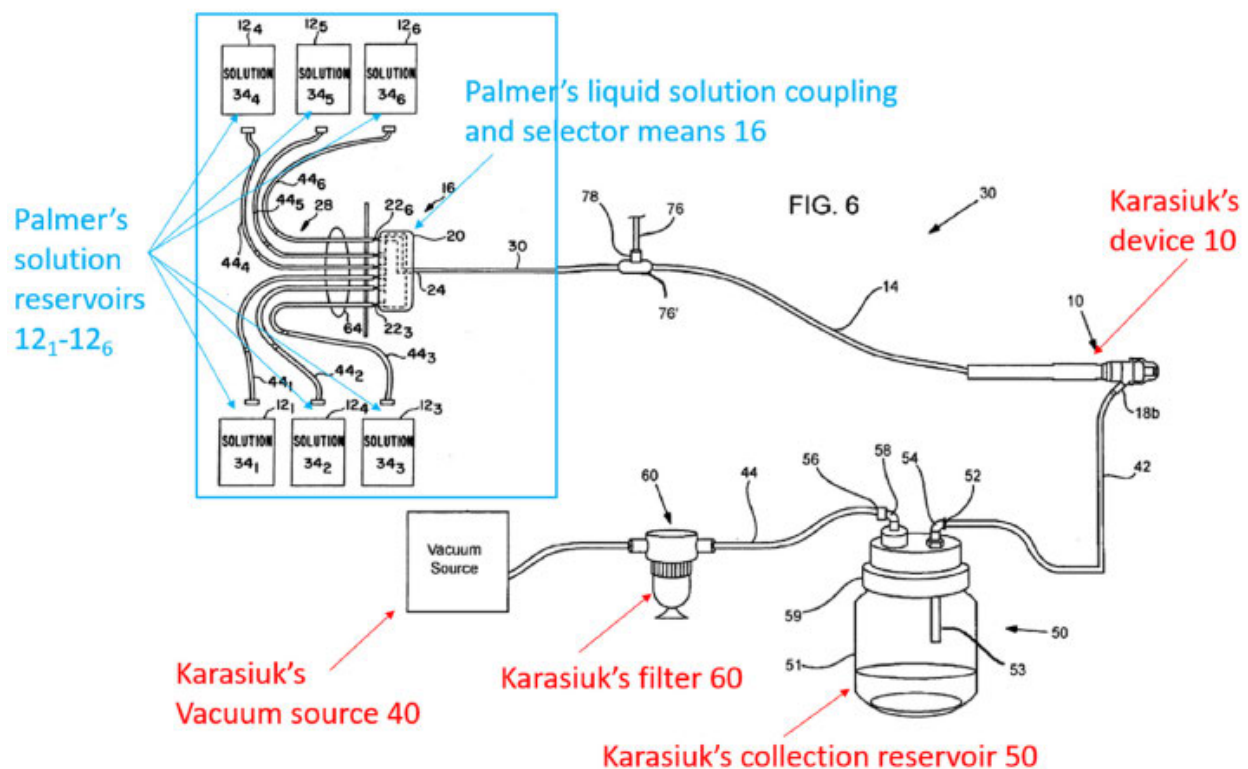
Petitioners' combination of Karasiuk with Palmer renders Karasiuk's system inoperable for its intended purpose. Ex.2001, ¶62. In the Karasiuk-Palmer combination, Palmer's solution reservoirs 12₁ - 12₆ are necessarily located below Karasiuk's breather line 76 and handpiece. *Id.* In this configuration, Karasiuk's vacuum source will draw only air through the breather line 76 along tube 14. *Id.* In Petitioners' proposed combination, the vacuum source would be unable to provide any vacuum force to draw material from Palmer's solution reservoirs to the handpiece. *Id.* This is because the air flow will take the path of least resistance to suck air from the breather line 76 as described by Karasiuk instead of fluid from Palmer's solution reservoirs 12 in Petitioners' proposed combination. A good analogy is having a crack in a drinking straw. *Id.*

This configuration in Petitioners' Karasiuk-Palmer combination changes the basic principles under which Karasiuk was designed to operate and renders it unsatisfactory for its intended purpose. *See Plas-Pak*, 600 Fed. Appx. at 759-60; Ex.2001, ¶62. Further, Petitioners' proposed arrangement clearly defeats the purpose Petitioners promoted behind the combination, "achiev[ing] benefits resulting from selection of different treatment solutions." Treatment solutions cannot be selected nor provide any benefits if they cannot reach the handpiece. For

these reasons, Petitioners have not established that claims would have been obvious under any grounds and the Board should deny institution.

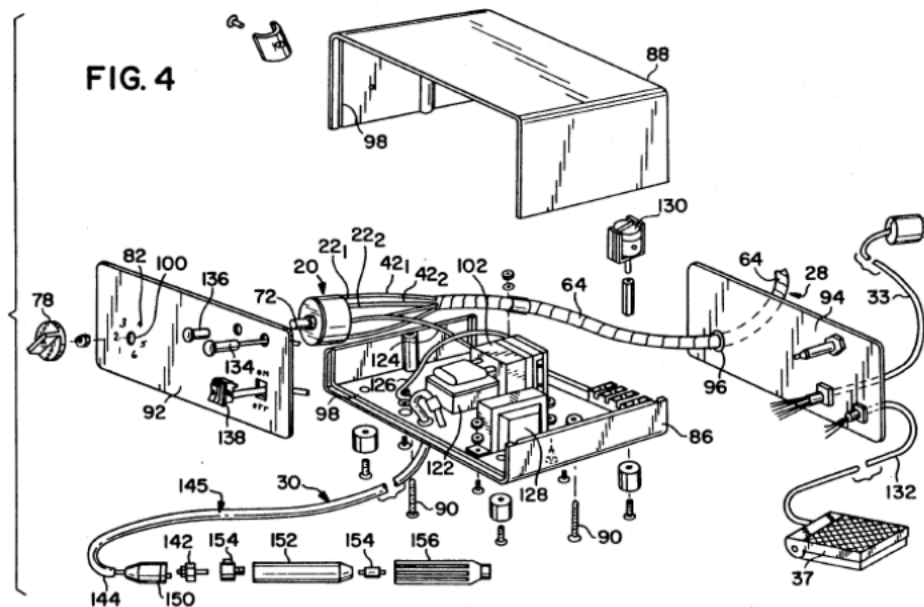
2. Karasiuk-Palmer's Tube Diameter Prevents Flow of Treatment Material to the Handpiece Assembly

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. Ex.2001, ¶¶64, 65.



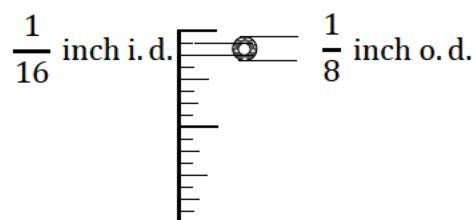
Karasiuk, Modified FIG. 6

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



Ex.1005, Fig. 4. Ex.2001, ¶66.

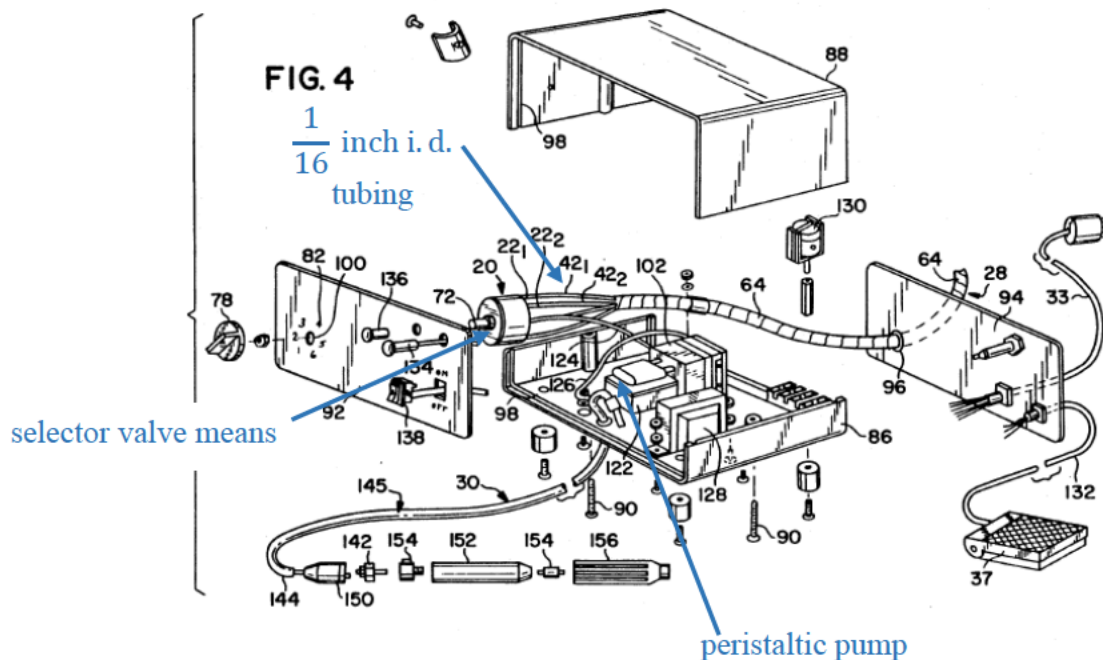
Palmer discloses that tubing with an outside diameter of $1/8^{\text{th}}$ inch and an inside diameter of $1/16^{\text{th}}$ inch is used in the six tubes 42 running between the solution reservoirs 12 and the selector valve means 20 located within the control unit enclosure and in tubing 126 running from the control unit enclosure 35 to the handpiece 14. *See* Ex.1005, 7:21-24, 9:17-19, 9:40-43. For perspective, Mr. Leinsing prepared the image below that shows the cross-sectional diameter of Palmer's tubing on the scale of an 8 1/2 x 11-inch sheet of paper:



Ex.2001, ¶66.

Given that Palmer's system is designed to produce high-velocity spray to irrigate a patient's mouth with a low volumetric output, tubing with an extremely narrow inside diameter of 1/16th inch is appropriate. Ex.2001, ¶67. Palmer's 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; Ex.2001, ¶68. 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. Ex.1005, 5:26-30; Ex.2001, ¶68. 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 12. Ex.2001, ¶67.

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



Ex.1005, Fig. 4 (annotated). Additionally, Palmer uses low-viscosity rinse solutions, minimizing any resistance from the liquid flowing through the tubing. *Id.*, 5:52-64; Ex.2001, ¶69.

In Petitioners' proposed combination of Karasiuk and Palmer, Palmer's small-diameter tubing renders the combined device inoperable. *Id.*, ¶70. 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. Ex.2001, ¶71. As a general matter, the pressure drop exhibited along a length of tubing is directly proportional to the length of the tubing. *Id.* 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. *Id.*

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:

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

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; Ex.2001, ¶72. As the equation above indicates, an increase in tubing length L and use of higher viscosity solutions (as used in hydrodermabrasion procedures) will increase the pressure drop or resistance to flow. *Id.* Moreover, as illustrated with the equation and explained by Mr. Leinsing, 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). Ex.2001, ¶72.

Additionally, 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;

Ex.2001, ¶73. Thus, even modest reductions in pipe diameter result in substantial increases in velocity (*e.g.*, halving the pipe's radius reduces the area by a factor of four, thereby quadrupling the velocity to maintain the same flow rate). *Id.*, 73, 74.

Thus, in addition to the issue of the breather line 76 discussed above, which prevents the vacuum source 40 from drawing suction at the solution reservoirs 12, Palmer's small-diameter tubing and the distance between Karasiuk's vacuum source 40 and Palmer's solution reservoirs 12, would inhibit the generation of suction at the solution reservoirs 12 in Petitioners' combination of Karasiuk and Palmer. Ex.2001, ¶76.

Moreover, Karasiuk discloses using lotion—often mixed with solid abrasive particles—as the treatment material in the reservoir 70. *See* Ex.1004, [0059]-[0061]. Lotions have a significantly higher viscosity than the rinse solutions used in Palmer's system. Ex.2001 ¶77; *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).

If a lotion were used in Palmer's solution reservoirs 12, it would encounter significant frictional losses (or drag) in Palmer's 1/16th inch diameter tubes, which run from the solution reservoirs 12 to the selector valve means 20 in the control unit enclosure 35. Ex.2001, ¶78. Palmer's tubing is too narrow to allow fluid flow to

the handpiece under vacuum pressure from Karasiuk's vacuum source 40. Even if some fluid managed to reach the handpiece, the resulting volumetric flow rate would be unacceptably low for use in a skin treatment procedure. *Id.*, ¶79.

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

Even if Petitioners were somehow permitted to fix these fatal flaws in the Karasiuk-Palmer combination discussed above, Petitioners' combination would still be inoperable. Ex.2001, ¶¶80-82. As explained above, Petitioners' proposed combination of Karasiuk and Palmer removes Palmer's peristaltic pump 18 and adds Karasiuk's vacuum source 40, which is positioned downstream of the handpiece. In doing so, Petitioners introduce another fatal flaw into the Karasiuk-Palmer system. *Id.*

Palmer's peristaltic pump 18 is located downstream of the selector valve means 20 and acts as a valve, preventing liquid from flowing from the solution reservoirs when the peristaltic pump is inactive. *Id.*, ¶81; *see* Ex.1005, 11:30-34 (Palmer explaining that is peristaltic pump "serves as a natural check valve."). Furthermore, Palmer's selector valve means 20, which Petitioners rely on for the claimed manifold, serves as an uninterrupted pathway from the selected solution reservoir.

With Palmer's peristaltic pump removed from Petitioners' combination system, the material in the selected solution reservoir would flow uncontrolled to or from the selected solution reservoir, even without activating the vacuum source. Ex.2001, ¶82. Thus, once again, these alterations would render the system inoperable. Therefore, Petitioners cannot meet their burden of showing that any claims of the '477 patent would have been obvious over the cited prior art.

H. Grounds 1A-1D: Palmer Does Not Disclose a Manifold System

In each of Grounds 1A-1D, the Petition relies on a combination of Karasiuk and Palmer (Pet., 1), but this combination fails to disclose a limitation required by all claims—namely, a “manifold system.” All independent claims recite a manifold system in fluid communication with multiple fluid containers. Limitation [1.1] in claim 1 recites “a manifold system in communication with a first container and at least a second container;” limitation [9.1] in claim 9 recites “a manifold system in communication with at least two containers;” and limitation [15.1] in claim 15 recites “a manifold system in communication with at least two containers.” Ex.2001, ¶83.

In Grounds 1A-1C, Petitioners rely on Palmer's “selector valve means 20” as allegedly satisfying the manifold limitations. But Palmer's selector valve means 20 cannot meet these limitations under the well-understood meaning of “manifold.” In the Petition, Petitioners recognize that a “manifold” has multiple openings under the

ordinary meaning. Palmer's selector valve means 20, in contrast, is limited to a one-input-one-output connection. Ultimately, Petitioners' argument contradicts its own definition of "manifold," finds no support in Palmer, and relies on impermissible hindsight. *See* Ex.2001, ¶84.

1. The Ordinary Meaning of "Manifold"

The term "manifold" is common in the mechanical arts. The ordinary meaning of manifold is a pipe or closed space in a machine that has multiple openings, such as multiple inlets and a single outlet, for passage of fluids. *See* Ex.2001, ¶¶85-86.

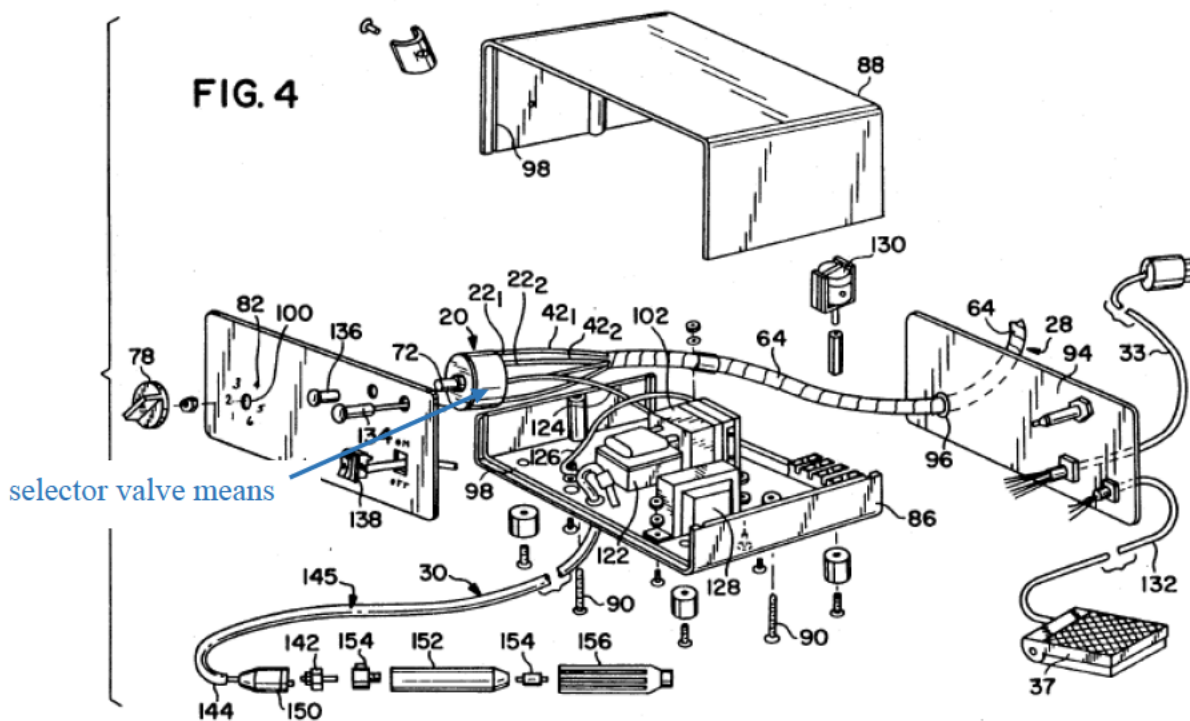
In accord with this commonly understood meaning, Petitioners cite a mechanical engineering dictionary in the Petition that defines "manifold" as "a chamber or pipe with many openings." Pet., 15, n.5 (citing Ex.1029, 5); *see also* Ex.1003, ¶107 n.2 (Ex.1029, 5). Furthermore, in IPR2025-00145 related to the '287 patent, Walbrink testified that a "manifold" requires multiple passageways (*e.g.*, "multiple inlets and a single outlet") and cannot be an object having only a single inlet and single outlet. Ex.2164, 59:10–62:21.

Thus, there can be no dispute regarding the ordinary meaning of "manifold" or that it applies to the claims of the '477 patent. Ex.2001, ¶87.

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

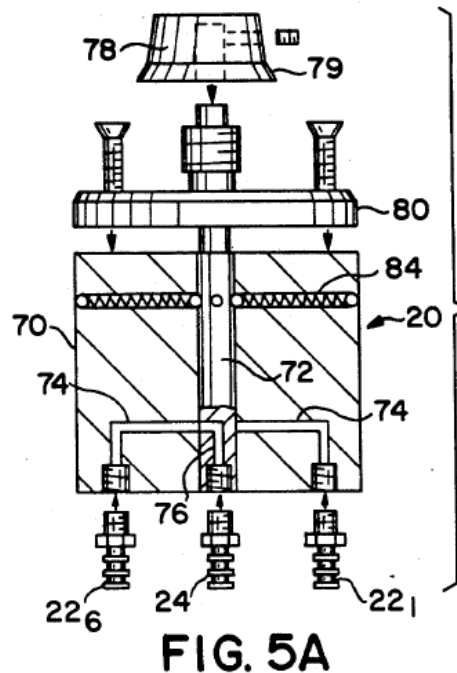
Petitioners assert that the manifold system limitations are met by Palmer’s “selector valve means 20.” *See* Pet., 15-23. But Petitioners’ argument fails under the well understood meaning of “manifold,” a meaning which Petitioners have adopted. Ex.2001, ¶88.

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



Ex.1005, Fig. 4 (annotated); Ex.2001, ¶89.

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

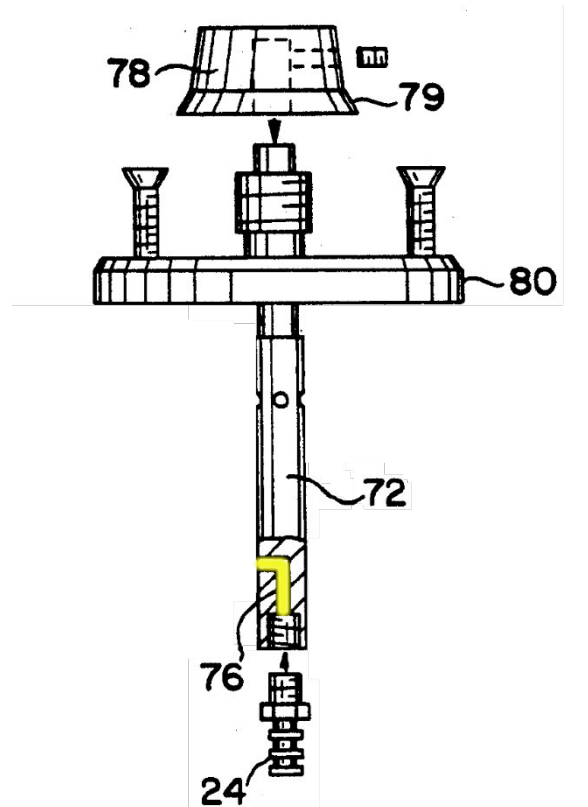


Ex.1005, Fig. 5A; Ex.2001, ¶89.

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

another end opening onto the cylindrical core surface in the plane of the inner ends of passages 74.” *Id.*, 8:13-18 (emphasis added). Ex.2001, ¶90.

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



Id., Fig. 5A excerpt (annotated); Ex.2001, ¶91.

When a user rotates the knob 78 on the front of the selector valve means 20, the central cylinder core 72 is “rotated until the end of the outlet passage 76 communicates with the particular inlet passage 74 corresponding to the inlet coupled to the desired irrigating solution.” Ex.1005, 8:45-48. “For example, when the knob is rotated so that the pointer 78 indicates the indicia designated ‘6’, the outlet passage

76 communicates with the inlet passage 74 which opens into the inlet port 22₆ which is coupled to the solution 34₆ contained in the reservoir 12₆.” Ex.1005, 8:48-53; *see also* Ex.2001, ¶92.

As illustrated in Fig. 5A, the selector valve means 20 connects the inlet port 22₆ to the outlet passage 76 (the connected path shown in green), while the inlet port 22₁ is disconnected and physically blocked from the outlet passage 76 (the disconnected path shown in red):

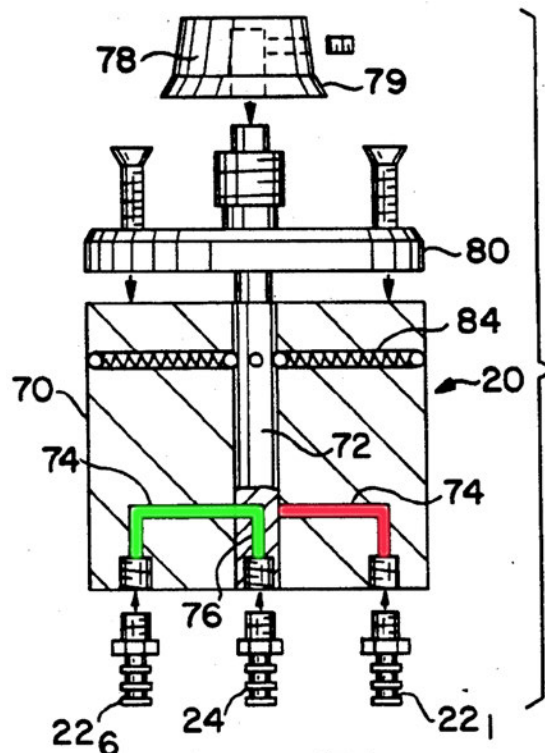


FIG. 5A

Ex.1005, Fig. 5 (annotated). The annotated figure also illustrates that the remaining inlet ports—22₂, 22₃, 22₄, 22₅—are disconnected and effectively isolated from the outlet passage 76. Ex.2001, ¶93. Palmer further explains the selector valve means

20 is a “means for coupling a selected **one** of the inputs 22 to **the** output 24.” Ex.1005, 5:1-9 (emphasis added). Thus, Palmer’s selector valve means 20 works specifically because it is **not** a manifold; it provides only a single, isolated pathway through the central cylinder core 72. Ex.2001, ¶93.

Accordingly, Palmer’s design is fundamentally distinct from a manifold, which, according to Petitioners’ own cited definition, requires “a chamber or pipe with **many** openings.” Pet., 15, n.5. Palmer’s selector valve means 20 is neither a chamber nor a pipe with **many** openings. And it has only a single, isolated pathway, as explained above. As such, Palmer’s selector valve means 20 does not meet the manifold system limitation in independent claims 1, 9, and 15, and the Petition fails to establish otherwise. Ex.2001, ¶94.

Furthermore, Walbrink admitted that Palmer cannot satisfy this “manifold system” limitation under his own understanding of the term “manifold.” Ex.2164, 75:1–77:13 (agreeing that “at any given time or any selection, the selector means has one of the selection tubes as the inlet and then the handpiece as the outlet” and agreeing “it can only have one solution tube as the inlet.”).

Recognizing this deficiency, the Petition proposes a modification to the Karasiuk-Palmer combination, which itself is flawed and relies on hindsight rather than objective reasoning based on the prior art. In Ground 1A, Petitioners argue that “a POSITA would have found it obvious to use a manifold system to implement

Palmer's functionality of switching treatment fluids." Pet., 20-21. It asserts that manifolds were, e.g., "well-known," "within a POSITA's general knowledge," one of "a finite number of identified, predictable solutions," and "an obvious design choice." *Id.*, 20-22. But these conclusory assertions do not establish that a POSITA **would have been motivated** to make such a substitution—only that a POSITA **could have**. See *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) ("[O]bviousness concerns whether a skilled artisan not only could have made but would have been motivated to make the combinations or modifications of prior art to arrive at the claimed invention.").

Critically, the Petition and expert declaration identify no shortcoming in Palmer's selector valve means 20 that would justify replacing it. Pet., 20-22; Ex.1003, ¶¶113-114. At most, the Petition contends a POSITA would have selected a manifold because "it eliminates the need of manual connecting/disconnecting and allows for a simpler handpiece design with one input." Pet., 22. However, Palmer's selector valve means 20 already eliminates manual connections, and the Petition and expert declaration fail to explain how a manifold could possibly simplify Karasiuk's handpiece design. Ex.2001, ¶95.

The Petition also argues that incorporating a manifold in the Karasiuk-Palmer combination "would have merely involved a simple substitution of one well-known element for another to obtain predictable results." Pet., 22. But this is inconsistent

with the Petition's own cited definition of a "manifold." A device that selectively connects one input to one output, like Palmer's selector valve means 20, is not equivalent to "a chamber or pipe with many openings." Replacing one with the other would require significant unaddressed structural and functional changes to accommodate the manifold's many openings. Ex.2001, ¶96. This is not a simple substitution.

Accordingly, Petitioners have failed to establish that Palmer discloses a manifold or that a POSITA would have modified Palmer to include one.

I. Grounds 1C-1D: Wunsch Does Not Cure Palmer's Deficiencies

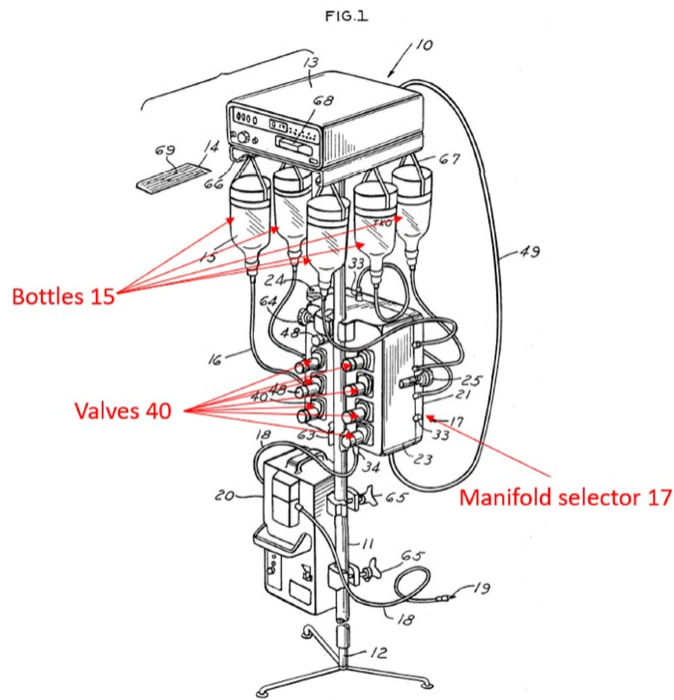
In Ground 1C, Petitioners tack on Wunsch to the combination of Karasiuk and Palmer in an attempt to cure Palmer's deficiencies. Pet., 1, 48-65. Indeed, Petitioners assert that a POSITA would have entirely replaced Palmer's liquid solution coupling and selector means 16 with Wunsch's manifold selector and sequencer-timer. Pet., 1, 51. But this proposed modification is illogical and clearly driven by hindsight. Ex.2001, ¶97.

First, Petitioners tout Wunsch's benefits as supposed motivation for selecting its manifold, but then when carrying over the manifold to the Karasiuk-Palmer combination, Petitioners neglect to carry over the component allegedly providing that benefit. Petitioners allege a POSITA would have been motivated because "Wunsch's manifold selector is automatically controlled by the sequence-timer to

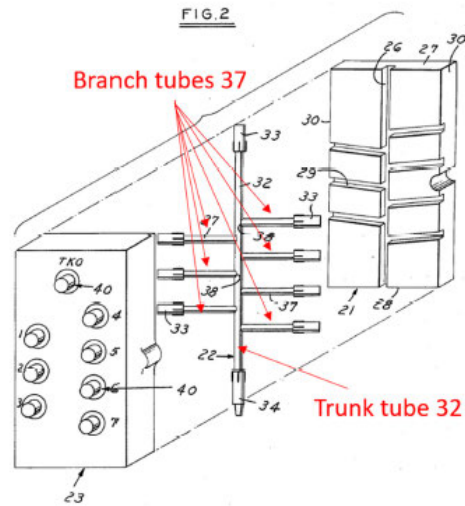
allow automatic dispensing of different treatment fluids.” Pet., 53. Wunsch makes clear that “[t]he quantity of solution dispensed is metered by a volumetric infusion pump.” Ex.1020, Abstract; *see also id.*, 7:57-65 (“[F]luid volume through the dispensing tube 18 is controlled by the volumetric infusion pump 20.”). Ex.2001, ¶99.

Yet, the Petition never incorporates Wunsch’s infusion pump when combining Wunsch with Karasiuk and Palmer, and thus provides no means of regulating Wunsch’s manifold selector through the sequencer-timer. *See* Pet., 54-55. Instead, Petitioners attempt to incorporate only “Wunsch’s manifold selector and sequence timer.” Pet., 51. Without this infusion pump, the automatic control would have no feedback loop and therefore could not function as intended. Ex.2001, ¶¶100-102.

Second, Petitioners never explain how Wunsch’s manifold selector and sequence timer could possibly be applied to the existing combination of Karasiuk and Palmer. Petitioners attempt to extract Wunsch’s manifold selector 17—with its manifold 22, including trunk tube 32 and a plurality of branch tubes 37—and apply it to the already overly complicated and problematic combination of Karasiuk and Palmer. Ex.2001, ¶103.



Wunsch, FIG. 1 (annotated)



Wunsch, FIG. 2 (annotated)

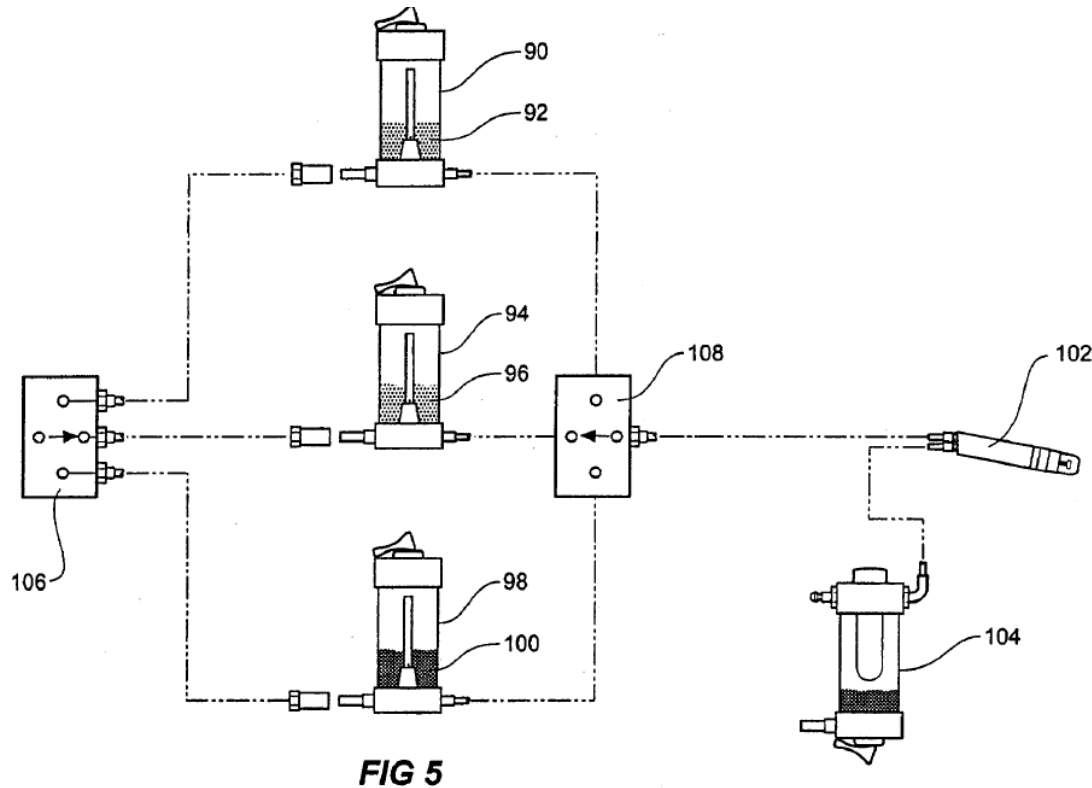
Pet., 49, 51.

Petitioners have not met their burden to show that a skilled artisan would have been motivated to make such a combination. Ex.2001, ¶104. Thus, Petitioners' backup theory relying on Wunsch for the manifold system also fails.

J. Grounds 2A-2B: Greenberg Does Not Disclose a Manifold System

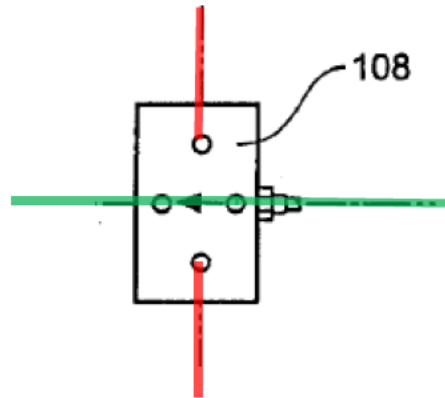
In Grounds 2A-2B, the Petition relies on Greenberg as allegedly disclosing the “manifold system” recited in all claims. Pet., 72-73. But, as with Palmer's selector control valve 20 in Grounds 1A-1D, the one-inlet-to-one-outlet valve that Petitioners point to in Greenberg for Grounds 2A-2B is not the claimed “manifold system.” Ex.2001, ¶¶127, 128.

Specifically, Petitioners point to valve 108 in Greenberg's Fig. 5 embodiment as allegedly meeting the "manifold system" limitations of the challenged claims. Pet., 72-73. Fig. 5 is shown below, with valve 108 positioned downstream of the supply containers 90, 94, and 98 and upstream of the handle 102. Ex.2001, ¶129



Ex.1006, Fig. 5. As Mr. Leinsing explains, a POSITA would have understood in reading Greenberg that valve 108 is a rotary valve or three-way valve, neither of which is a manifold. Ex.2001, ¶130. The Fig. 5 schematic shows that valve 108 includes only a single outlet line on the downstream side of the valve and includes a

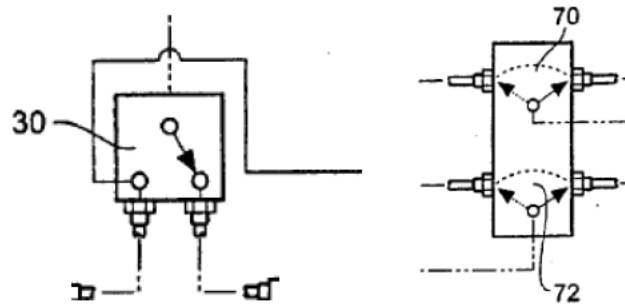
selector for the upstream side represented by the arrow on the valve, which permits selection of a single inlet line entering the valve.



Ex.1006, Fig. 5 (excerpted and annotated); Ex.2001, ¶130. Thus, like Palmer’s selector valve means 20, Greenberg’s valve 108 works specifically because it is *not* a manifold; it provides only a single, isolated pathway through the valve. Ex.2001, ¶131.

Indeed, none of Greenberg’s embodiments discloses a manifold system. Rather, Greenberg’s other embodiments also disclose use of a switch or valve, such as a rotary valve. For example, the embodiment in Figs. 1-2 includes “switch 30,” which Greenberg describes as “control[ing] *a solenoid* that switches the vacuum pump from operatively being connected either to the first or second assembly.” Ex.1006, [0050] (emphasis added). Similarly, the Fig. 3 embodiment includes “valves 70 and 72,” which Greenberg indicates are “adapted to operate in tandem and that control the coupling of the pneumatic source with the relevant supply and

recovery containers.” *Id.*, [0065]. Each of valves 70 and 72 is a single-inlet-to-single-outlet valve, rather than a manifold.



Ex.1006, Fig. 2 (excerpt), Fig. 3 (excerpt); Ex.2001, ¶132.

According to Petitioners’ own cited definition, a manifold requires “a chamber or pipe with *many* openings.” Pet., 15, n.5 (emphasis added). Greenberg’s valve design is fundamentally distinct from a manifold, as Greenberg’s valve 108 is neither a chamber nor a pipe with *many* openings, and it has only a single, isolated pathway. Accordingly, Greenberg’s valve 108 does not meet the manifold system limitations in independent claims 1, 9, and 15. Ex.2001, ¶133.

Walbrink has confirmed that Greenberg, like Palmer, discloses “only one inlet going to the outlet to the handpiece,” and thus cannot satisfy the “manifold system” limitation under his own understanding of the term. Ex.2164, 86:3–23. Accordingly, Greenberg cannot satisfy the claimed “manifold system” as the Petition alleges.

Recognizing this deficiency, Petitioners again propose a backup theory to modify Greenberg, but the modification is flawed and relies on hindsight rather than

objective reasoning based on the prior art. Petitioners argue that “a POSITA would have found it obvious to use a manifold system to implement Greenberg’s functionality of switching treatment materials.” Pet., 74. It asserts that manifolds were, e.g., “well-known,” “within a POSITA’s general knowledge,” and one of “a finite number of identified, predictable solutions.” *Id.*, 74-75. But these conclusory assertions do not establish that a POSITA **would have been motivated** to make such a substitution—only that a POSITA **could have**. See *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (“[O]bviousness concerns whether a skilled artisan not only could have made but would have been motivated to make the combinations or modifications of prior art to arrive at the claimed invention.”); Ex.2001, ¶134.

Critically, the Petition and expert declaration identify no shortcoming in Greenberg’s valve 108 that would justify replacing it. Pet., 74-75; Ex.1003, ¶¶273-274. At most, the Petition contends a POSITA would have selected a manifold because “it eliminates the need of manual connecting/disconnecting and allows for a simpler handpiece design with one input.” Pet., 74-75. However, Greenberg’s valve 108 already eliminates manual connections, and the Petition and expert declaration fail to explain how a manifold system could possibly simplify Greenberg’s handpiece design. Ex.2001, ¶135.

The Petition also argues that incorporating a manifold in Greenberg “would have merely involved a simple substitution of one well-known element for another to obtain predictable results.” Pet., 75. But this is inconsistent with the Petition’s own cited definition of a “manifold.” A device that selectively connects one input to one output, like Greenberg’s valve 108, is not equivalent to “a chamber or pipe with many openings.” Replacing one with the other would require significant unaddressed structural and functional changes to accommodate the manifold’s many openings. Ex.2001, ¶136. This is not a simple substitution.

Accordingly, Petitioner has failed to establish that Greenberg discloses a manifold system or that a POSITA would have modified Greenberg to include one.

K. Grounds 2A-2B: Greenberg Does Not Disclose the Claimed “Treatment Material”

The independent claims of the '477 patent recite that the manifold system is “in fluid communication” with the handpiece assembly and “in communication with” multiple containers, and also recite that the multiple containers are “configured to contain a treatment material.” Greenberg does not disclose the claimed “treatment material.” Although no express construction is needed, the Board should determine

that the ordinary meaning of “treatment material” in the context of the specification and claims excludes dry abrasive particles.⁵ Ex.2001, ¶138.

As an initial matter, Petitioners and Mr. Walbrink appreciate that the Examiner, during prosecution of the '477 patent, chose not to rely on Greenberg in rejecting the “treatment material” and “fluid communication” limitations because Greenberg discloses using only dry abrasive particles and fails to disclose these limitations. Pet. 4; Ex.1003, ¶51. Yet, Petitioners have taken the position that Greenberg’s solid abrasive particles constitute a “fluid” and satisfy the “treatment material” limitations. *See* Pet., 78 (“[A] POSITA would have understood and found obvious that Greenberg’s *‘particles’ constitute ‘fluid’* within the meaning of the '477 patent”), 78-79 (emphasis added) (characterizing dry abrasive particles as within the scope of “treatment material”); Ex.2001, ¶140.

Petitioners’ interpretation of “treatment material” and “fluid” is inconsistent with the specification. Petitioners interpret the following specification paragraph as somehow broadening the scope of “fluid” and “treatment material” to cover solid abrasive particles.

⁵ As Petitioners note, “claim terms need only be construed to the extent necessary to resolve the controversy.” Pet., 2 (citing *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011)).

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, 5:38-45 (cited by Pet., 78). Citing this passage, Petitioners argue that “Greenberg’s abrasive particles” correspond to “**a plurality of fine solids.**” Pet., 78 (emphasis by Petitioners).

Contrary to Petitioners’ contention, the ’477 patent expressly distinguishes prior-art microdermabrasion technology using abrasive particles. The specification explains that with microdermabrasion, “the surface of the skin is removed due to mechanical rubbing by a handpiece emitting a stream of sand or grit” to wear away “cell layers of the skin.” Ex.1001, 1:58-65. It 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.*, 1:63-65. Microdermabrasion can be a painful experience and due to its harsh nature, can often leave patients with redness. *Id.*, 1:46-50 (describing dermabrasion as painful and leaving the skin “red and raw-looking”).

In contrast to microdermabrasion’s stream of sand or grit, the ’477 patent discloses a system for treating skin that “deliver[s] *fluid* from at least one of the

plurality of fluid sources to the handpiece assembly.” *Id.*, 2:25-28. Consistent with this distinction, the claims of the '477 patent do not cover prior-art microdermabrasion and, instead, jettison the painful procedure for hydrodermabrasion. The systems claimed by the '477 patent wholly eliminate resurfacing the skin with sandpaper-like blasts of abrasive particles.

The specification distinguishes between “wet” and “dry” modes on the basis that the “wet” mode applies treatment materials to the skin and 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.*

Ex.1001, 6:19-27 (emphasis added).

Further demonstrating that the treatment materials are not dry solid particles, the specification explains “the handpiece assemblies can be used *without treatment material*, i.e., the handpiece can be used *in a dry procedure.*” Ex.1001, 13:20-23 (emphasis added). That the inventors described the procedure without treatment

material as a “dry procedure” demonstrates that the treatment materials are not dry solid particles.

The specification also correlates the “effectiveness of the fluid” on the skin with the amount of time the “active ingredients of the treatment material” are retained on the skin:

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*.

Ex.1001, 10:1-9 (emphases added). Thus, the identified functions of longer fluid contact times—absorption of ingredients, hydration, and serum retention—are not functions performed by solids. And, 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.*, 15:53-16:25.

Moreover, Petitioners have not—and cannot—allege that the discussion of “treatment material” and “fluid” in the specification amounts to an inventor’s definitional lexicography. The mere fact that a sentence starts with the phrase “as used herein, the term...” does not per se render the sentence lexicography. *See*

Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343, 1355 (Fed. Cir. 2003)

(holding that statement in specification starting with “[a]s used herein, ‘analyte’ refers....” is not lexicography). Furthermore, “the written description's use of ‘may also include,’ ‘e.g.,’ ‘such as,’ and ‘etc. makes clear the patentee did not intend” lexicography. *Baxalta Inc. v. Genentech, Inc.* 972 F.3d 1341, 1549 (Fed. Cir. 2020).

Thus, based on the intrinsic record, the Board should reject Petitioners’ attempt to broaden “treatment material” to encompass the dry solid particles disclosed in Greenberg. If the Board determines a formal claim construction is necessary, the Board should find that “treatment material” has its plain and ordinary meaning in view of the specification and that such meaning does not encompass dry solid particles. Ex.2001, ¶141.

Such an evaluation is sufficient to resolve the parties’ dispute and find that Greenberg does not disclose the claimed “treatment material.” Indeed, Petitioners do not dispute that Greenberg discloses only dry particles and Petitioners never propose any modification of Greenberg’s microdermabrasion system to use anything other than dry particles. *See* Pet., 75-76 (citing Greenberg for its disclosure of different types of abrasive particles). Ex.2001, ¶143.

L. Grounds 2A-2B: A POSITA Would Not Have Been Motivated to Combine Greenberg's Different Embodiments

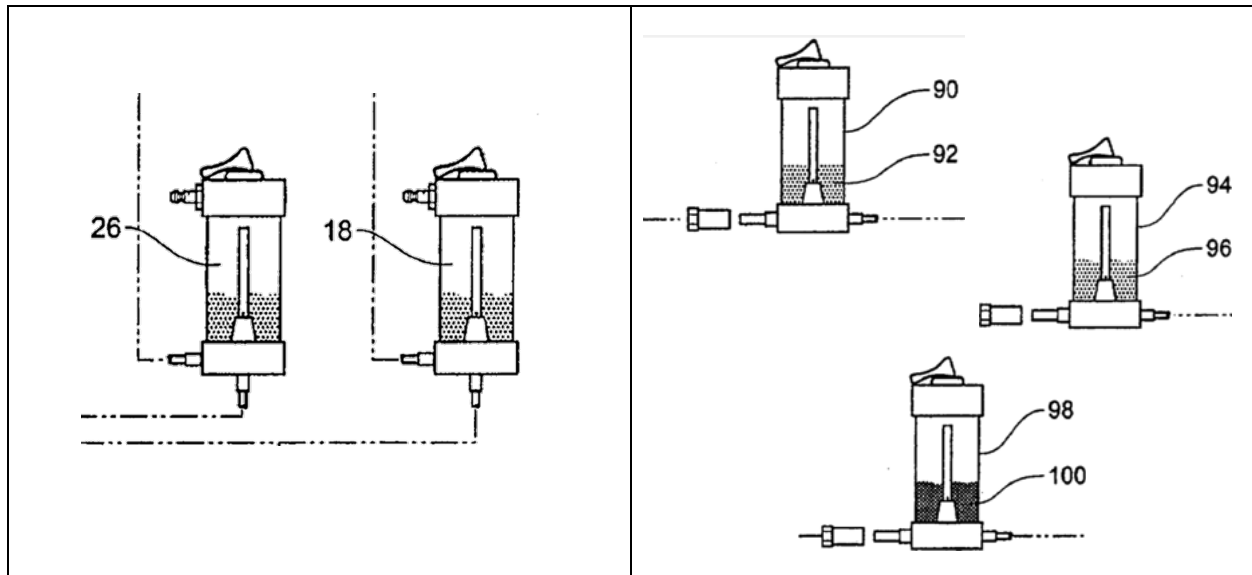
In Grounds 2A-2B, Petitioners must rely on different structures from multiple different embodiments in Greenberg in an attempt to cover all of the claim limitations in the challenged claims. However, Petitioners fail to provide any motivation to combine these different structures, and a POSITA would have lacked such motivation. Petitioners' combination of these different structures is driven by hindsight alone. Ex.2001, ¶144.

For example, Petitioners assert that 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., 68. Petitioners further assert, "[a]s Mr. Walbrink describes, other structures described with respect to FIGS. 1-4 would be similarly applicable for the FIG. 5 implementation." *Id.*, 69 (citing Ex.1003, ¶75).⁶ Petitioners next assert that Fig. 3's "vacuum pump 12" is added to Fig. 5's schematic in an attempt to satisfy limitations [1.4], [1.5], and [1.7]. Pet., 80-83, 85-87; Ex.2001, ¶145.

⁶ For the "other structures," Mr. Simon describes only Fig. 1's "tube 20" to be used in Fig. 5. Ex.1003, ¶75.

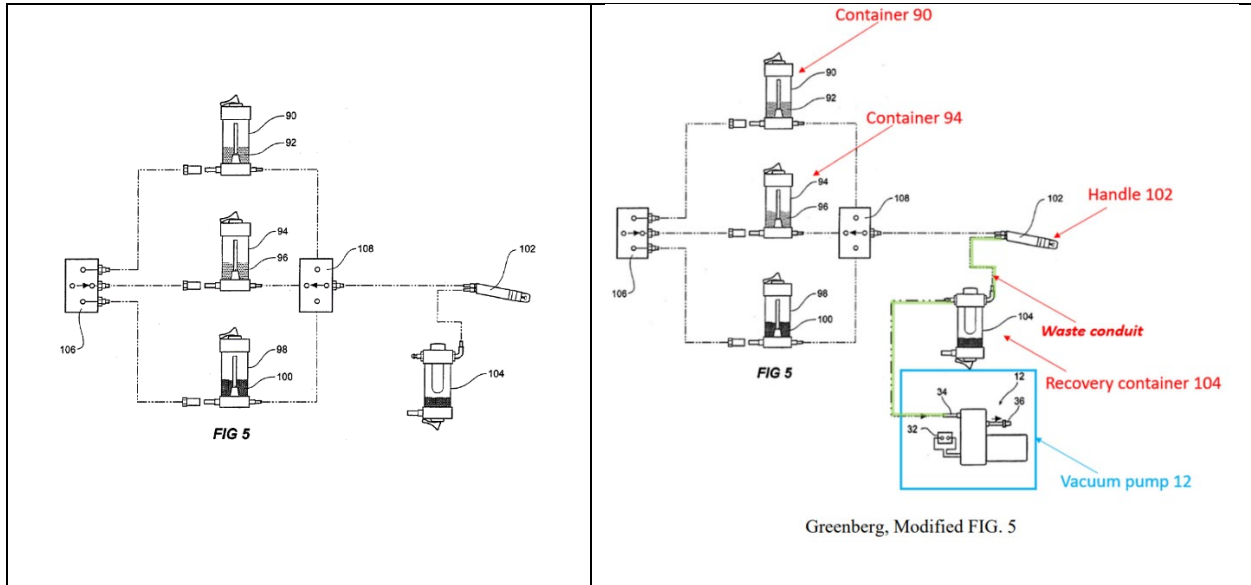
But Petitioners and Mr. Walbrink fail to provide any explanation of how or why any of these structures from Figs. 1-4 would be combined or implemented in Greenberg's Fig. 5 embodiment. *See* Pet., 68 (alleging Fig. 5's implementation would have been "readily incorporated" into Fig. 5 but failing to provide any motivation to do so). Mr. Walbrink essentially repeats the Petition's description and also fails to provide any motivation for the combination of different structures. *See* Ex.1003, ¶133.

In fact, Greenberg itself indicates that these structures in the Figs. 1-4 embodiments are not compatible with the Fig. 5 embodiment. For example, Greenberg states that "[w]herever possible, the same reference numbers will be used through the drawings and the following description to refer to the same and like parts." Ex.1006, [0048]. Throughout the Figs. 1-4 embodiments, Greenberg uses the same reference numbers for the supply containers, recovery containers, and handles. But in the Fig. 5 embodiment, Greenberg uses different reference numbers for Fig. 5's supply containers, recovery container, and handle. *Compare, e.g.,* Ex.1006, Figs. 1-4 (reference numbers 18, 26 for supply containers) *with* Fig. 5 (reference numbers 90, 94, 98 for supply containers). Ex.2001, ¶147. Furthermore, Greenberg indicates in Fig. 5 that those supply containers are structurally different than, e.g., the Fig. 2 supply containers, each having different outlet configurations:



Ex.1006, Figs. 2 (excerpted), Fig. 5 (excerpted); Ex.2001, ¶148.

Petitioners' combination of different Greenberg embodiments is particularly problematic in Petitioners' addition of the vacuum pump to Greenberg's vacuum-free Fig. 5 embodiment. In addressing the "vacuum source" claimed in limitation [1.4], Petitioners point to Fig. 3's "vacuum pump 12." Pet., 78. And, when addressing limitations [1.5] and [1.7] related to the function and orientation of the vacuum source, 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., 82, 86; Ex.2001, ¶149.

Petitioners, however, never address whether a POSITA would have even been motivated to modify Fig. 5 in this manner. For limitation [1.5], Petitioners essentially just repeat the claim language to allege a POSITA would find the modification obvious: “A POSITA would have understood and found obvious that Greenberg’s vacuum pump 12 is fluidly connected to recovery container 104.” Pet. 81. Likewise, for limitation [1.7], Petitioners again merely repeat the language of the claim—without any additional evidence—to allege a POSITA would have found the motivation obvious. *Id.*, 86-87; Ex.2001, ¶150. Petitioners have not met their burden to show that a POSITA would have been motivated to combine these different embodiments. *See Belden*, 805 F.3d at 1073 (“[O]bviousness concerns whether a skilled artisan not only could have made but would have been motivated

to make the combinations or modifications of prior art to arrive at the claimed invention.”).

And in fact, a POSITA would not have been motivated to add a vacuum source to Greenberg’s Fig. 5 embodiment. Ex.2001, ¶151. On its own, Greenberg’s Fig. 5 embodiment lacks any type of pneumatic source, whether a vacuum or a compressor. However, 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. *Id.*, ¶151. 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] (emphasis added). 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 the handle 102. Ex.2001, ¶151.

Petitioners and Mr. Walbrink have not shown in Ground 2A that a POSITA would have been motivated to combine Greenberg’s different embodiments to arrive at the claimed invention. I note that in Ground 2B, Petitioners add only Trueba to

the combination 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. *See* Ex.1008, 1:7-13; Ex.2001, ¶152.

VI. OBJECTIVE INDICIA INDEPENDENTLY CONFIRM NONOBVIOUSNESS

Petitioners attempt to reconstruct the invention with hindsight. But objective, real-world evidence tells a different story—one of genuine innovation, not obviousness. HydraFacial's patented systems reshaped the industry by displacing outdated technologies, securing and maintaining market leadership, and prompting widespread copying by competitors.

These objective indicia are not ancillary; they constitute “independent evidence of nonobviousness” that the Board must consider under *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013) (secondary considerations “are not just a cumulative or confirmatory part of the obviousness calculus but constitute[] independent evidence of nonobviousness.”). Walbrink confirmed that these objective indicia can be important in the obviousness analysis, but he admitted he did not consider any objective indicia in forming his opinions. Ex.2150, 33:1-34:25.

This real-world evidence—emerging only after the invention entered the marketplace—avoids the distorting lens of hindsight and confirms that the claimed inventions were not obvious at the time they were made.

A. Nexus Is Established Between the Claimed Inventions and the Evidence

HydraFacial readily demonstrates a nexus between the claimed inventions and the evidence, both through (1) the presumption of nexus and (2) affirmative proof that the evidence is directly attributable to the claimed invention. *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1210 (Fed. Cir. 2023).

The nexus presumption applies here because HydraFacial’s commercial delivery systems—the Tower, Allegro, Elite, and Syndeo (“HydraFacial Systems”)—all embody and are coextensive with the challenged claims of the ’052 patent. HydraFacial’s expert, Leinsing, evaluated the HydraFacial Systems and confirmed that each system satisfies the limitations of the challenged claims, thereby embodying them. Ex.2004, ¶¶1-274.

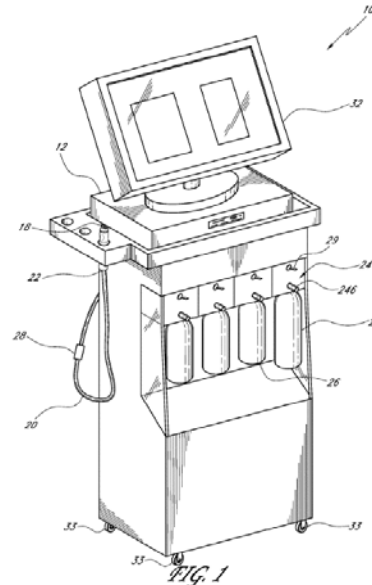
Leinsing further demonstrated that the HydraFacial Systems are essentially the claimed invention itself and therefore coextensive with the claims. *Id.*, ¶¶275-280. Each HydraFacial System aligns with the scope of protection in the claims, as each is a “skin treatment system” that incorporates the claimed features. *Id.*, ¶1-274. Indeed, the Tower—HydraFacial’s original multi-container system protected by the

'477 patent and first sold in 2005—directly reflects the claimed invention, as illustrated by the '477 patent's Figure 1:

Tower Product



'477 Patent, Fig. 1



Ex.2033, 1; Ex.1001, Fig.1; Ex.2004 ¶277. The HydraFacial Systems incorporate the key claimed features, including: (1) multiple fluid containers; (2) a manifold system; (3) a supply conduit placing the manifold system in fluid communication with a handpiece assembly; (4) a vacuum source; (5) a waste conduit in fluid communication with the handpiece assembly; and (6) at least one control to permit control of a flow of treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly. Ex.2004, ¶276.

Furthermore, the HydraFacial Systems do not include any critical unclaimed features. *Id.*, ¶278. While the HydraFacial Systems may include ancillary

components such as a light therapy handpiece, those accessories are not central to the operation of the HydraFacial Systems. *Id.* The HydraFacial Systems have consistently been marketed as hydrodermabrasion systems. *See id.* (citing Ex.2038 (Tower), Ex.2039 (Tower), Ex.2040 (Tower), Ex.2041 (Tower), Ex.2042 (Tower), Ex.2043 (Tower), Ex.2044 (Elite), Ex.2045 (Elite), Ex.2046 (Elite), Ex.2047 (Allegro)). Furthermore, red and blue light therapy—sometimes offered as an accessory—can be performed by for less expensive devices. Ex.2015; Ex.2004, ¶278. The significant features of the HydraFacial Systems are those claimed in the '477 patent, and these features are coextensive with the challenged claims. Ex.2004, ¶¶276-280.

To the extent Petitioners argue that the handpiece tips are critical features covered by different patents or materially affect the functionality of the HydraFacial Systems, that argument is misplaced. The claims recite “a handpiece configured to contact skin tissue of a subject,” where a tip is part of the claimed handpiece/handpiece assembly, as the specification confirms. *See, e.g.*, Ex.1001, Figs.1-4, 5:42-46, 5:57-60, 6:44-45, 6:49-53, 7:50-54, 10:39-11:3, 19:25-28, 19:39-42; Ex.2004, ¶279.

Because the HydraFacial Systems embody and are coextensive with the challenged claims, the presumption of nexus applies and the burden shifts to Petitioners for rebuttal. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*,

229 F.3d 1120, 1130 (Fed. Cir. 2000). “The presumed nexus cannot be rebutted with mere argument; evidence must be put forth.” *Id.*

Even apart from this presumption, nexus is independently established, as demonstrated below, where the evidence confirms that the HydraFacial Systems’ commercial success and competitor copying flow directly from the patented features. *Id.*

B. Commercial Success of the Patented Systems

The commercial success of HydraFacial’s patented systems is indisputable. Ex.2003, ¶¶1-39.

1. Significant Revenue and Growth

From 2005, when HydraFacial introduced the Tower, through the second quarter of 2024, the HydraFacial Systems generated extraordinary global sales, achieving nearly [REDACTED] dollars in revenue, as reflected in the table below.

**NET WORLDWIDE SALES REVENUES BY
HYDRAFACIAL PRACTICING SYSTEM
(2005 TO JUNE 2024)**

Model Name	Period	Worldwide Revenues
[A]	[B]	[C]
[1] Tower	2005 - 2023	\$
[2] Allegro	2012 - Q2 2024	\$
[3] Elite	2016 - Q2 2024	\$
[4] Syndeo	2022 -Q2 2024	\$
[5] Total	2005 - Q2 2024	\$

Ex.2010; Ex.2009, ¶¶7-8; Ex.2003, ¶31.

As HydraFacial's economic expert, Dr. Seth, explains, the HydraFacial Systems have demonstrated sustained and significant growth, driven by increasing unit sales and revenues worldwide. Ex.2003, ¶30. The graph below shows this trend, showing worldwide net unit sales and net revenues for the HydraFacial Systems from 2005 to 2023.



Ex.2010; Ex.2003, ¶30. As Dr. Seth explains, sales of the HydraFacial Systems have consistently increased across all years, with revenues growing on average by [REDACTED] annually between 2005 and 2023. Ex.2003, ¶30. The launch of HydraFacial's Elite system in 2016 and Syndeo system in 2022 further accelerated this trajectory, producing [REDACTED] and [REDACTED] increases in worldwide net sales revenues, respectively. *Id.*

Moreover, HydraFacial Systems' growth, measured by global net revenues, has far outpaced the global beauty industry's growth. Ex.2003, ¶34. For example, while the global cosmetics market achieved a compound annual growth rate ("CAGR") of approximately 4% between 2012 and 2023, the HydraFacial Systems (Allegro, Elite, and Syndeo) achieved a CAGR of [REDACTED] during the same period. *Id.*

HydraFacial's growth was not only faster but exponential compared to the broader market, demonstrating that its success is driven by the patented innovations rather than general industry trends.

2. Market Share Dominance

HydraFacial created—and continues to dominate—the hydrodermabrasion market. Ex.2003, ¶¶32-34. As HydraFacial explained in SEC filings, “HydraFacial created the category of hydradermabrasion with its patented delivery system (‘Delivery System’) that cleanses, extracts, and hydrates the skin with proprietary solutions and serums.” Ex.2140, 7; Ex.2003, ¶33.

Before HydraFacial's entry, microdermabrasion was widely used as a skin treatment technique, but it carried significant drawbacks, including being messy and often painful. Ex.2013, 219; Ex.2012, 238; Ex.2001, ¶¶54-55. Today, demand for traditional microdermabrasion has sharply declined, even though it is less expensive than HydraFacial treatments. According to a dermatologist interviewed by *Allure* magazine in 2018, “newer takes on microdermabrasion, such as the HydraFacial, are rendering the traditional treatment outdated.” Ex.2139; *Id.* (“...there's been such a great evolution in peels and treatments like the HydraFacial, that I wouldn't go back to it and recommend it over other options.”); Ex.2003, ¶32.

HydraFacial's dominance is confirmed by market share data. Ex.2009, ¶9; Ex.2003, ¶33; Ex.2145. In 2024, HydraFacial held a [REDACTED] share of sales and a [REDACTED]

share of visits in the broadly defined market that includes microdermabrasion. *Id.* Thus, HydraFacial not only created the hydrodermabrasion market but has also effectively displaced microdermabrasion, commanding over [REDACTED] of the market in that category. *Id.*

3. Comparative Success Against Non-Practicing Products

The commercial trajectory of HydraFacial's patented systems, compared to the non-practicing Nectre system, provides compelling evidence that it was the patented features that drove success.

The Nectre, launched in 2008, was a single-container system that did not practice the '477 patent's claims. Ex.2004, ¶¶281-323.



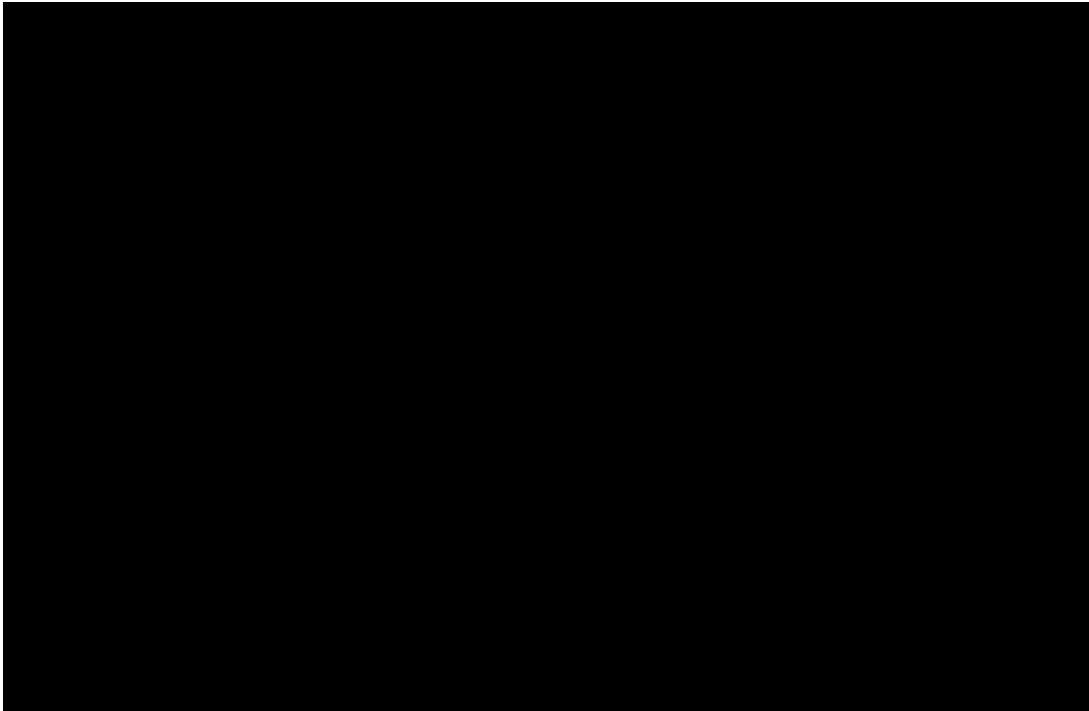
Ex.2036. Like Karasiuk, the Nectre used only a single container, requiring clinicians to manually swap the container during treatment to change treatment solutions. Ex.2036, 11; Ex.2004, ¶289. In contrast, the HydraFacial Systems employed a

multi-container configuration—including a manifold—that enabled seamless and efficient treatments without interruption, making the HydraFacial Systems far more desirable. Except for this critical difference, the Nectre is comparable in every other material respect to the HydraFacial Systems, even using the same tips. Ex.2004, ¶¶281-323.

The marketplace response confirms the importance of the patented features. The Nectre was a commercial failure, generating only [REDACTED] in lifetime revenue and experiencing a negative CAGR of [REDACTED] Ex.2003, ¶¶37-38. By contrast, during the same period, the Tower and Allegro systems—practicing the '052 patent—generated nearly [REDACTED] in revenue and sustained growth at a [REDACTED] CAGR. *Id.*, ¶37.

The figure below illustrates this clear contrast, showing Nectre's worldwide net sales revenues over its product life cycle (2006-2013) compared with Tower and Allegro over the same period.

**WORLDWIDE NET REVENUES FROM THE NECTRE AND
HYDRAFACIAL SYSTEMS (TOWER AND ALLEGRO)
(2006-2013)**



Ex.2003, ¶37.

The stark disparity between the Nectre and the patented systems provides direct proof of nexus: it was the patented features—not unclaimed design choices—that drove HydraFacial’s commercial success. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1350 (Fed. Cir. 2012) (finding commercial success and nexus established by comparing patented dual-activity oil rig with unpatented single-activity rig).

C. Copying by Competitors

Copying by competitors is recognized as “strong evidence of nonobviousness.” *Volvo*, 81 F.4th at 1213. “[W]here there is evidence of actual

copying efforts, that evidence is always relevant.” *Liqwd, Inc. v. L’Oreal USA, Inc.*, 941 F.3d 1133, 1138 (Fed. Cir. 2019). Direct evidence—including “photos of patented features” and “access and similarity to a patented product”—is probative of copying (*id.* at 1137), even if it predates the patent at issue. *Id.* at 1138 (vacating Board decision that disregarded “actual copying” where Board had held evidence of copying irrelevant because patent owner had not shown competitor “copied a patented product”).

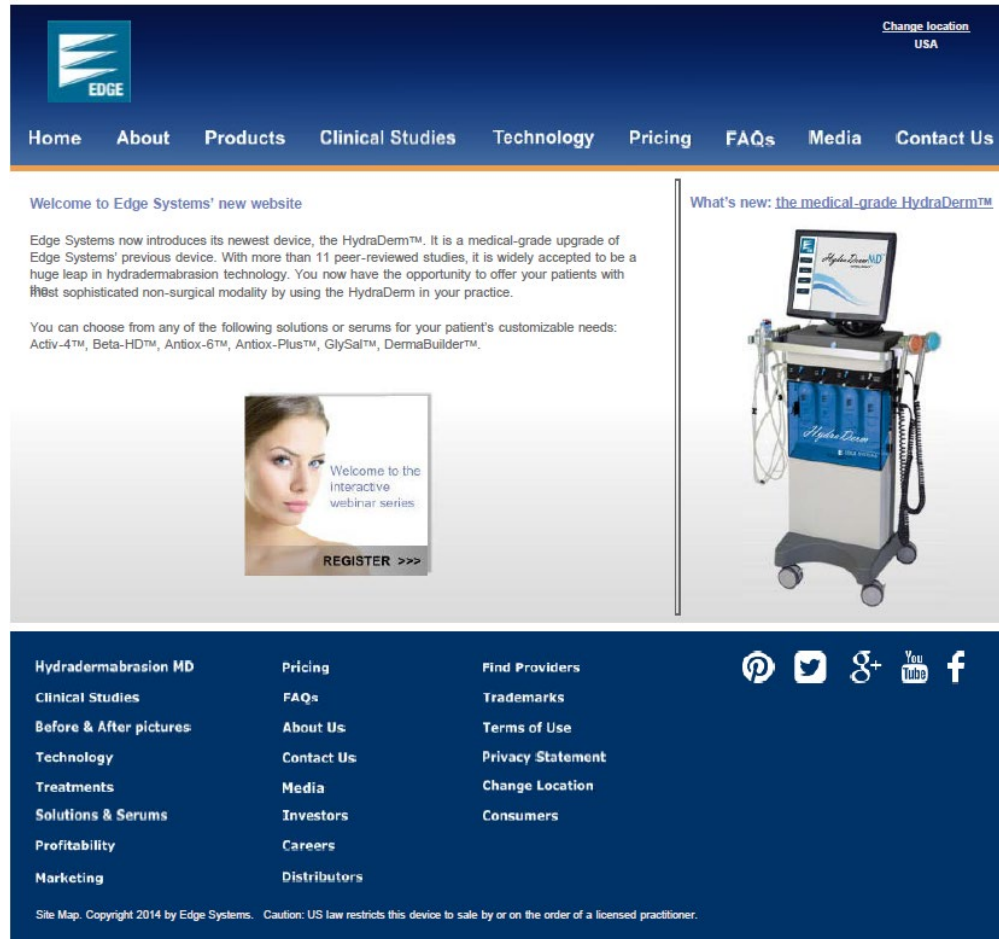
That is precisely what occurred here. In 2014, Rafael Aguila (“Aguila”) marketed and sold his “HydraDerm” product, which was a near-exact copy of HydraFacial’s Tower system. Ex.2004, ¶¶330-332. As explained above, the Tower embodies the challenged claims of the ’477 patent, and Aguila’s knockoff product duplicated those claimed features wholesale. *Id.*, ¶¶332-338.

Aguila’s own website confirmed his intent: the “HydraDerm” product was designed to look and function like the Tower.

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Edge Systems -- Originator of Hydradermabrasion Technology, World Leader in Microdermabrasion.



Ex.2154, 3 (attorney declaration attaching website printout); Ex.2155, 2. Aguila promoted his knockoff device as “the next generation in microdermabrasion technology due to the simultaneous dermal infusion of medicinal products and crystal-free exfoliation” and “the first medical device that uses the ‘4-in-1’ technology of Cleansing, Exfoliation, Extraction, and Infusion.” Ex.2155, 4, 12. His website depicted the device with multiple treatment containers and emphasized the use of multiple treatment solutions. *Id.* Aguila further described the “pneumatic

action of the vacuum” and the use of a handpiece to deliver treatments with the multiple solutions. *Id.*, 7. These are precisely the integrated treatment capabilities claimed in the '477 patent and embodied in the Tower. Ex.2004, ¶¶333-334.

HydraFacial sought and obtained a TRO and a preliminary injunction against Aguila. Ex.2005, 8-9; Ex.2007; Ex.2008. The court also granted HydraFacial’s summary judgment motion, characterizing Aguila’s device as a “bootleg,” “clone,” “copycat”—“the quintessential example” of copying another’s intellectual property. Ex.2005, 1. The summary judgment order included side-by-side comparisons of Aguila’s HydraDerm and HydraFacial’s Tower:



EDGE HYDRAFACIAL® PRODUCT



DEFENDANT’S ACCUSED PRODUCT

Ex.2005, 6; Ex.2004, ¶¶335-338. Aguila’s device contained the same structural features—including a block, fluid control member, collection lumen, and multiple treatment solution containers integrated into the system. Ex.2004, ¶337. The resemblance was so close that customers believed they had purchased a genuine HydraFacial system. Ex.2005, 7-8; Ex.2004, ¶¶337-338.

The district court entered final judgment against Aguila, and the Federal Circuit affirmed on appeal, quoting the district court's "apt summation" of Aguila's copying: "Bootleg. Clone. Copycat. Imitation. Knock-off. Palm-Off." *Edge Sys. LLC v. Aguila*, 708 F. App'x 998, 999 (Fed. Cir. 2017).

Aguila's slavish copying is itself direct proof of nexus. His device was a near-identical replica of the Tower, and the Tower is coextensive with the claims of the '287 patent. *Liqwd*, 941 F.3d at 1138 ("[W]here there is evidence of actual copying efforts, that evidence is always relevant."); Ex.2004, ¶338.

Other competitors also copied HydraFacial's claimed invention. HydraFacial obtained a consent judgment in *Edge Systems LLC, et al., v. Image MicroDerm Inc.*, 2:17-cv-08699 (C.D. Cal.), where the defendant admitted to infringing HydraFacial's U.S. Patent No. 9,550,052 ("'052 patent"). Dkt. 81, ¶¶7, 9. The '052 patent, like the '477 patent, is directed to multi-container hydrodermabrasion systems, and the defendant admitted its multi-container BioXFusion device infringes:



Dkt. 80-1 (Ex. A).

VII. CONCLUSION

For the foregoing reasons, HydraFacial respectfully requests that the Board deny institution of the Petition.

Respectfully submitted,

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Dated: October 17, 2025

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CERTIFICATE OF TYPE-VOLUME LIMITATIONS
UNDER 37 C.F.R. § 42.24

The undersigned certifies that the foregoing **PATENT OWNER PRELIMINARY RESPONSE** contains 13,581 words, exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), and therefore complies with the type-volume limitations of 37 C.F.R. §42.24(a).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of **PATENT OWNER PRELIMINARY RESPONSE** is being served on October 17, 2025, via email pursuant to 37 C.F.R. § 42.6(e), to counsel for Petitioner as addressed below:

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