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Title: DEVICES AND METHODS FOR TREATING SKIN

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**DECLARATION OF ERIC SIMON IN SUPPORT OF PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 12,052,607**

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I, Eric Simon, of Salt Lake City, Utah, declare that:

I. ASSIGNMENT

1. I have been retained on behalf of Eunsung Global Corp (“Eunsung”) to offer technical opinions related to U.S. Patent No. 12,052,607 (“The ’607 patent”) (EUNSUNG-1001). I understand that Eunsung is requesting that the Patent Trial and Appeal Board (“PTAB” or “Board”) to institute an *inter partes* review (“IPR”) proceeding of the ’607 patent.

2. I have been asked to provide my independent analysis of the ’607 patent in light of the prior art publications cited in this declaration.

3. I am not and never have been, an employee of Eunsung. I received no compensation for this declaration beyond my normal hourly compensation based on my time actually spent analyzing the ’607 patent, the prior art publications cited below, and issues related thereto, and I will not receive any added compensation based on the outcome of any IPR or other proceeding involving the ’607 patent.

II. QUALIFICATIONS

4. A detailed description of my professional qualifications, including a list of publications, patents, awards, and professional activities, is contained in my curriculum vitae, a copy of which is attached as **Appendix A**.

5. I received a Master of Engineering (M.Eng.) in Bioengineering and a Bachelor of Science (B.S.) in Materials Science and Engineering, both degrees

from the University of Utah. My focus during my master's degree was on device design, mechanical engineering, and manufacturing processes; my focus during my bachelor's degree was on biomaterials and materials processing. In addition to various traditional engineering disciplines, my studies included physics, chemistry, ergonomics, optics, and applied biomaterials, I also had extensive coursework in the biological sciences including neurobiology, cell biology, and medical-school level anatomy and physiology.

6. I have been designing biomedical products since 1981. I am the President, Principal Design Engineer, and Founder of Dexterity Design, a product design, development, and engineering firm specializing in the design and development of biomedical and biotechnical products, including dermatology and cosmetology devices. The product scope of Dexterity Design is primarily biomedical and biotechnical devices and instrumentation, both for therapeutics and diagnostics. I have also designed and developed consumer, industrial, and recreational products.

7. I have experience designing and implementing a wide range of medical therapeutic and diagnostic devices including those used in orthopedics, dermatology, cosmetology, ophthalmology, and cardiovascular medicine. These encompass implantables, procedural tools, and extra-corporeals, both durable and disposable. I also have experience in designing biotechnical instruments used in

proteomics, genomics, and other areas of molecular analysis, as well as cell culture systems. I am often called upon to develop mechanical components and enclosures for these products and am very familiar with the design and the materials, prototyping, and manufacturing thereof. I have expertise in fluidics and microfluidics, both liquid and gaseous, utilized in these products. Furthermore, I work closely with electronic designers/engineers and programmers and have solid working knowledge of the use of microcontrollers and other circuitry for device control, and the programming requirements they encumber.

8. My experience with the development of cosmetology/dermatology devices includes the design, prototyping, testing, and manufacturing of various products for dermal and subdermal conditions. These conditions include various disease-based skin disorders, as well as dermal rejuvenation for aging and sun damage. I have also designed and developed products to reduce tissue pain and damage to near-surface structures such as tendons, ligaments, and muscles such as ultrasonic and photonic therapeutic devices.

9. Pertaining to the case herein, I have designed and developed microdermabrasion devices which utilize abrasive particles fluidized into an air stream which is directed onto the skin of the patient/customer for purposes of removing epidermal cells. Typically, these devices are used for cosmetology to induce skin regeneration within the dermis and lower epidermis which in turn

gives the recipient the appearance of more youthful skin. In some cases, the device may be powerful enough to abrade deeper into the skin tissue, making it useful for remediating scars and tattoo removal. The devices I designed all used vacuum (negative pressure) to draw the abrasive grit from a supply vessel, fluidize the grit in a separate chamber, carburate it into an air stream, and deliver it into a handpiece where it is then directed onto the skin. Concurrently, impacted abrasive grit, debrided skin cells, and body fluids are withdrawn from the site of impact and then returned to the device and deposited into a waste containment vessel for later disposal. During the course of this development, I was required to read and understand numerous prior art patents relating to dermabrasion, microdermabrasion, and other forms of fluidized-stream surface abrasion (e.g., those used for industrial sand-blasting and bead-blasting). I also studied various microdermabrasion apparatuses offered from competitive manufacturers. A product based on this design and development efforts was offered for sale and generated good sales and user reviews for many years; I was listed as an inventor on two utility patents and two design patents relating to this product.

10. To date, I am a listed inventor on 22 U.S. patents, issued and pending. As mentioned, several of these include microdermabrasion apparatuses, and others relating to dermal and subdermal therapeutics.

11. Please see my CV, attached hereto as **Appendix A**, for further

information.

III. SUMMARY OF CONCLUSIONS FORMED

12. This Declaration explains the conclusions that I have formed based on my analysis. To summarize those conclusions:

- **Ground 1A:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 1-5, 7, 9, and 20 of the '607 patent are rendered obvious by Karasiuk and Palmer.
- **Ground 1B:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 2, 4, and 20 of the '607 patent are rendered obvious by Karasiuk, Palmer, and Waldron.
- **Ground 1C:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 1-20 of the '607 patent are rendered obvious by Karasiuk, Palmer, and Trueba.
- **Ground 1D:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 2, 4, 12, 14, and 20 of the '607 patent are rendered obvious by Karasiuk, Palmer, Trueba, and Waldron.
- **Ground 2A:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 1 and 3-5 of the '607 patent are rendered obvious by Greenberg.

- **Ground 2B:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claim 4 of the '607 patent is rendered obvious by Greenberg and Waldron.
- **Ground 2C:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 1-20 of the '607 patent are rendered obvious by Greenberg and Trueba.
- **Ground 2D:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 2, 4, 12, 14, and 20 of the '607 patent are rendered obvious by Greenberg, Trueba, and Waldron.

IV. BACKGROUND KNOWLEDGE PRIOR TO THE PRIORITY DATE OF THE '607 PATENT

13. I have been informed that a person of ordinary skill in the art is a hypothetical person who is presumed to have the skill and experience of an ordinary worker in the field at the time of the alleged invention. Based on my knowledge and experience in the field and my review of the '607 patent and file history, I believe that a person having ordinary skill in the art (POSITA) at the time of the alleged invention would have had an undergraduate degree (B.S.) in Mechanical Engineering or equivalent knowledge, training, or experience, with two years of work experience in the design of mechanical products, design of fluidic systems, and/or the design of devices intended for medical or

cosmetological applications. Additional education or industry experience may compensate for a deficit in one of the other aspects of the requirements stated above

14. My analysis and conclusions set forth in this declaration are based on the perspective of a person of ordinary skill in the art having this level of knowledge and skill as of the date of the alleged invention of the '607 patent. Based on instruction from Counsel, I have applied **December 30, 2005 (“Critical Date”)**, as the date of the alleged invention of the '607 patent.

V. LEGAL PRINCIPLES

15. I am not a lawyer and I will not provide any legal opinions in this IPR. Although I am not a lawyer, I have been advised that certain legal standards are to be applied by technical experts in forming opinions regarding the meaning and validity of patent claims.

A. Claim construction

16. I understand that claim terms are generally given their plain and ordinary meaning in light of the patent's specification and file history as understood by a POSITA at the time of the purported invention. In that regard, I understand that the best indicator of claim meaning is its usage in the context of the patent specification as understood by a POSITA. I further understand that the words of the claims should be given their plain meaning unless that meaning is

inconsistent with the patent specification or the patent's history of examination before the Patent Office. I also understand that the words of the claims should be interpreted as they would have been interpreted by a POSITA at the time of the invention was made (not today).

B. Priority

17. I understand that a continuation application is a later-filed application that has the same disclosure (specification and figures) as an earlier-filed application to which the later-filed application claims priority. A continuation is generally entitled to the same priority date as the earlier-filed application to which it claims priority.

C. Anticipation

18. I understand that a patent claim is invalid as anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. I also understand that, to anticipate, the reference must teach all of the limitations arranged or combined in the same way as recited in the claim.

19. With respect to inherency, I understand that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Instead, the inherent characteristic must necessarily flow from the teaching of the prior art.

D. Obviousness

20. I understand that a patent claim is invalid if the claimed invention would have been obvious to a person of ordinary skill in the field at the time of the purported invention, which is often considered the time the application was filed. Thus, even if all of the claim limitations are not found in a single prior art reference that anticipates the claim, the claim can still be invalid.

21. To obtain a patent, a claimed invention must have, as of the priority date, been nonobvious in view of the prior art in the field. I understand that an invention is obvious when the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

22. I understand that, to prove that prior art or a combination of prior art renders a patent obvious it is necessary to: (1) identify the particular references that, singly or in combination, make the patent obvious; (2) specifically identify which elements of the patent claim appear in each of the asserted references; and (3) explain a motivation, teaching, need, market pressure or other legitimate reason that would have inspired a person of ordinary skill in the art to combine prior art references to solve a problem.

23. I also understand that certain objective indicia can be important

evidence regarding whether a patent is obvious or nonobvious. Such indicia include:

- Commercial success of products covered by the patent claims;
- A long-felt need for the invention;
- Failed attempts by others to make the invention;
- Copying of the invention by others in the field;
- Unexpected results achieved by the invention as compared to the closest prior art;
- Praise of the invention by the infringer or others in the field;
- The taking of licenses under the patent by others;
- Expressions of surprise by experts and those skilled in the art at the making of the invention; and
- The patentee proceeded contrary to the accepted wisdom of the prior art.

24. To the extent these factors have been brought to my attention, if at all, I have taken them into consideration in rendering my opinions and conclusions.

VI. MATERIALS CONSIDERED

25. Based on my above-described experience, I believe that I am considered to be an expert in the field. Also, based on my experiences, I understand and know of the capabilities of persons of ordinary skill in the field during the early 1990s–2010s, and I have worked closely with persons in the field

during that time frame.

26. As part of my independent analysis for this declaration, I have considered the following: the background knowledge/technologies that were commonly known to persons of ordinary skill in this art during the time before the Critical Date; my own knowledge and experiences gained from my work experience in the field of the '607 patent and related disciplines; and my experience in working with others involved in this field and related disciplines.

27. In addition, I have analyzed the following publications and materials:

- EUNSUNG-1001 U.S. Pat. No. 12,052,607 to Ignon (“the '607 patent”)
- EUNSUNG-1002 Excerpts from the Prosecution History of the '607 patent (“the Prosecution History”)
- EUNSUNG-1004 U.S. Patent Publication No. 2003/0212415 (“Karasiuk”)
- EUNSUNG-1005 U.S. Patent No. 5,199,604 (“Palmer”)
- EUNSUNG-1006 U.S. Patent Publication No. 2003/0093089 (“Greenberg”)
- EUNSUNG-1007 U.S. Patent No. 6,390,815 (“Pond”)
- EUNSUNG-1008 U.S. Patent No. 6,684,880 (“Trueba”)
- EUNSUNG-1009 U.S. Patent No. 4,512,764 (“Wunsch 1982”)
- EUNSUNG-1010 U.S. Patent Publication No. 2003/0018252 (“Duchon”)
- EUNSUNG-1011 U.S. Patent No. 4,215,476 (“Armstrong”)
- EUNSUNG-1012 Friedman, et al., Chemical peels, dermabrasion, and laser

therapy, Disease-a-Month 55.4 (2009): 223-235 (“Friedman”)

- EUNSUNG-1013 Burgess, Cheryl M., Cosmetic dermatology, Heidelberg, Germany: Springer, 2005 (“Burgess”)
- EUNSUNG-1014 Pickering, J. A., Touch-sensitive screens: the technologies and their application, International Journal of Man-Machine Studies 25.3 (1986): 249-269 (“Pickering”)
- EUNSUNG-1015 Friedman, Mark J. et al., The AMSA injection: A new concept for local anesthesia of maxillary teeth using a computer-controlled injection system. Quintessence Int 29 (1998): 297-3 (“Friedman 1998”)
- EUNSUNG-1016 Lee, Woan-Ruoh, et al., Lasers and microdermabrasion enhance and control topical delivery of vitamin C, Journal of investigative dermatology 121.5 (2003): 1118-1125 (“Lee”)
- EUNSUNG-1017 U.S. Patent No. 9,550,052 (“the ’052 patent”)
- EUNSUNG-1018 U.S. Patent No. 11,446,477 (“the ’477 patent”)
- EUNSUNG-1019 U.S. Patent No. 6,428,518 (“Brengele”)
- EUNSUNG-1020 U.S. Patent No. 4,559,036 (“Wunsch”)
- EUNSUNG-1021 U.S. Patent No. 6,099,511 (“Devos”)
- EUNSUNG-1022 U.S. Patent No. 5,163,902 (“Lynn”)
- EUNSUNG-1023 U.S. Patent No. 5,190,525 (“Oswald”)
- EUNSUNG-1024 U.S. Patent No. 6,673,082 (“Mallett”)

- EUNSUNG-1025 Rajan, Poonam, et al., Skin barrier changes induced by aluminum oxide and sodium chloride microdermabrasion, *Dermatologic surgery* 28.5 (2002): 390-393 (“Rajan”)
- EUNSUNG-1026 Karimipour, Darius J., et al., Molecular analysis of aggressive microdermabrasion in photoaged skin, *Archives of dermatology* 145.10 (2009): 1114-1122 (“Karimipour”)
- EUNSUNG-1027 U.S. Patent No. 6,241,739 (“Waldron-739”)
- EUNSUNG-1028 U.S. Patent No. 6,926,681 (“Ramey”)
- EUNSUNG-1029 U.S. Patent No. 6,641,591 (“Shadduck”)
- EUNSUNG-1030 Ron M. Shelton, *Prevention of Cross-Contamination When Using Microdermabrasion Equipment*, 72 CUTIS 266 (2003) (“Shelton”)
- EUNSUNG-1031 Walter K. Nahm et al., *Microdermabrasion for Treatment of Photoaging*, in PHOTOAGING 217 (Darrell S. Rigel et al. eds., 2004) (“Nahm”)
- EUNSUNG-1032 U.S. Patent No. 6,562,050 (“Owen”)
- EUNSUNG-1033 U.S. Patent No. 6,500,183 (“Waldron”)

VII. TECHNOLOGY OVERVIEW

A. Microdermabrasion

28. Dermabrasion mechanically removes the upper layer of skin to treat

various skin conditions including wrinkles, acne scars, uneven skin surfaces, and pigmentary disorders of photoaging. EUNSUNG-1012, 6; EUNSUNG-1013, 57.

Microdermabrasion, a variation of dermabrasion, typically relies on two basic functions: “(1) superficially abrading the skin with fine, sharp particles or “crystals” (aluminum oxide, salt, or sodium bicarbonate) suspended in an airstream and actuated via positive- or negative-flowing pressure, and (2) a vacuum closed-loop suction device to remove the crystals, along with dead skin, oil, and surface debris.” EUNSUNG-1013, 84. “The intensity of the treatment, as determined by the number of passes and level of suction, is chosen based on the condition being treated.” EUNSUNG-1013, 86. After treatment, the skin can be rinsed with tepid water and a moisturizer with adequate sunscreen applied. EUNSUNG-1013, 86.

29. As an alternative to laser resurfacing, chemical peels, and dermabrasion, microdermabrasion is indicated for similar skin issues but with the limitation of having relatively superficial results. EUNSUNG-1013, 85.

Microdermabrasion, described as a “skin polishing,” is used for atrophic acne scars, mild facial rhytids, clogged pores, traumatic scars, enlarged pores, brown spots, stretch marks, melasma, keratosis pilaris, and to improve skin texture. *Id.*

Microdermabrasion has also been used to prime the skin for superficial chemical peels by stripping the stratum corneum to ensure more even absorption. *Id.* When used in conjunction with microdermabrasion, traditional superficial chemical

peeling agents. *Id.*

30. Prior to treatment, the area is cleansed and allowed to dry completely. EUNSUNG-1013, 85. Vacuum level and crystal pressure may be determined by testing an area of nonfacial skin, but patient tolerance can also dictate an adjustment in the power setting. EUNSUNG-1013, 85-86. The first pass is performed by allowing gentle suction of the skin into the hand piece as it is made to glide along the skin surface. EUNSUNG-1013, 86. The surface area being treated is stretched taut by the clinician's free hand to avoid excessive suction in any one area, which can cause an abrasion or pinpoint bleeding. *Id.* A second pass is made at a right angle to the first, and if more passes are required, they should continue to follow this alternating pattern to avoid streaking. *Id.* Reducing the level of suction and or number of passes may be necessary around the eyes and other delicate areas of the face. *Id.* The intensity of the treatment, as determined by the number of passes and level of suction, is chosen based on the condition being treated. *Id.*

31. When the treatment is completed, the residual crystals should be gently brushed off the skin in the direction away from the eyes so as to prevent eye irritation. EUNSUNG-1013, 86. The skin can then be rinsed with tepid water and a moisturizer with adequate sunscreen applied. *Id.* Patients are instructed to avoid keratolytic agents, including retinoids, alpha-hydroxy acids, and benzoyl peroxides

3 days before and 3 days following the treatment. *Id.* They are asked to avoid waxing, electrolysis, and laser hair removal 1 week before treatment, and excessive sun exposure 2 weeks before treatment. *Id.* All patients are given prophylaxis for HSV 1 day before and 2 days following the treatment using standard oral antiviral therapy. *Id.*

32. The particle size of the aluminum oxide crystals used for microdermabrasion are significantly larger than those for dental use (100–120 μm versus 24–50 μm), and the smaller particles used for dental air abrasion have not been found to pose a significant health hazard. EUNSUNG-1013, 86.

33. Particle-based microdermabrasion was first developed in Italy in 1985 and first gained FDA clearance in 1996. EUNSUNG-1025, 1. Being about 40 years old, the science and technology of dermabrasion has evolved into various forms intended to maximize positive treatment outcomes for the patient/customer, simplify use of the apparatus for the user (physician/technician/cosmetologist/esthetician), and provide other benefits such as reduced cost of consumables and reduced time of treatment, and reduced amount of stray particles which may be irritating to both the user and the customer.

34. Customarily, a "crystal" microdermabrasion system includes a pump, a connecting tube, a hand piece, and a vacuum. While the pump creates a high-pressure stream of inert crystals (aluminum oxide, magnesium oxide, sodium

chloride, or sodium bicarbonate) to abrade the skin, the vacuum removes the crystals and exfoliated skin cells.

35. A simplified embodiment of the traditional microdermabrasion systems precludes use of a positive pressure pump to actuate the crystals, instead using only a vacuum source to “draw” the crystals from a reservoir, fluidize them into an airstream, and direct them onto the skin through the use of an applicator or handpiece. Once the crystals have impacted the skin, they are immediately drawn into a return line (through the same vacuum source as they were actuated onto the skin) and deposited into a waste receptable positioned upstream from the vacuum source. The advantage of this vacuum-based system is that a positive pressure pump is not needed, thereby reducing cost and complexity, as well as obviating the need to balance flows between the particle feed line and the particle/waste removal line. Additionally, a tip having an orifice is positioned on the skin-contact end of the handpiece and the flow of particles only occurs when the orifice is occluded by the skin, thereby closing the vacuum circuit and inducing airflow (with particles) through the system. In this manner, the particles only flow when the handpiece tip is placed on the skin treatment area and flow stops when the tip is removed (and the path is opened), thus creating an automatic flow/no-flow switch functionality. The device embodied in Karasiuk is this type of vacuum-based apparatus. Note that the tip may be a separate component (to facilitate disposability, cleaning, and

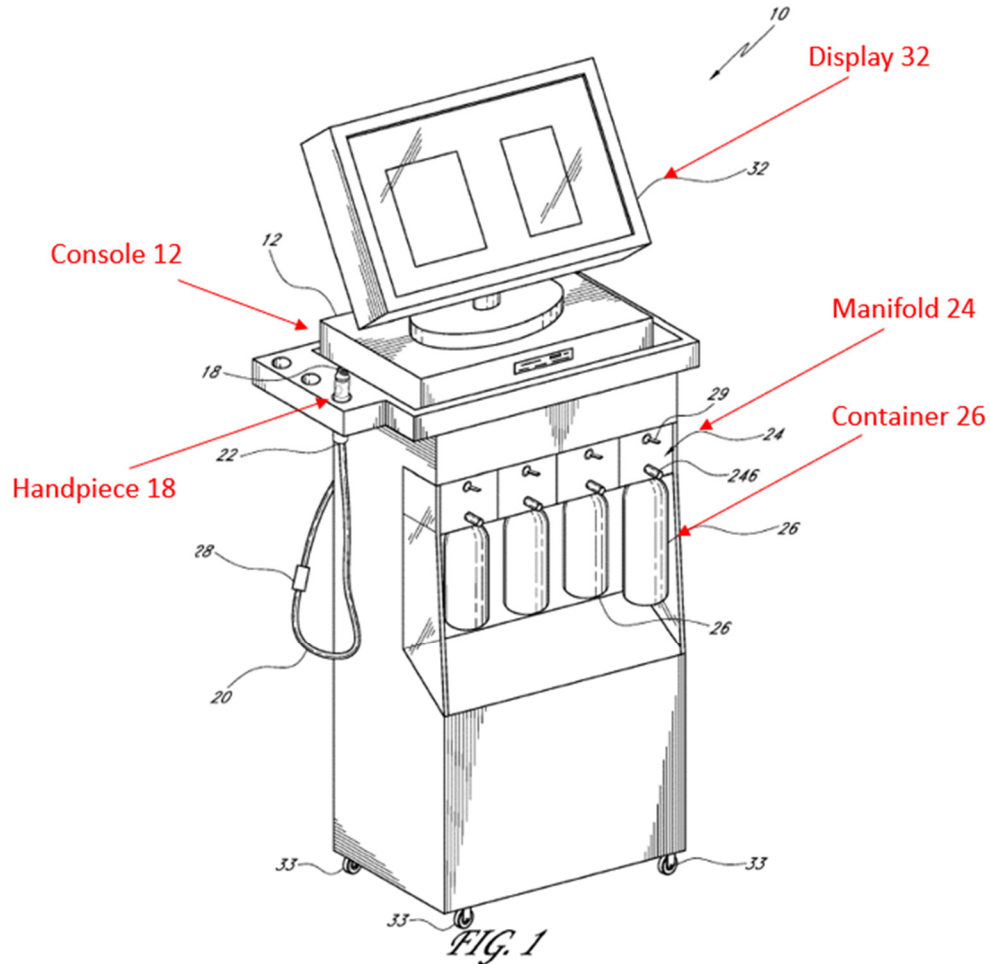
manufacturability) or may be integral to the working end of the handpiece.

36. In another embodiment, the inert crystals can alternately be replaced by a roughened surface of the handpiece tip, commonly known as a diamond microdermabrasion system. EUNSUNG-1026, 1. This type of surface-based system was introduced in the early 2000's. EUNSUNG-1027, Abstract, claim 1.

37. Microdermabrasion typically utilizes a gas, usually air, to entrain or fluidize the abrasive particles into an airstream and deliver those particles at a controlled concentration and velocity to the skin. However, the use of condensed fluids (i.e., liquids) such as water, saline, and other aqueous liquids, as well as non-aqueous liquids, may be employed. Likewise, semi-liquid condensed fluids, such as gels or slurries, may also be employed. The abrasive particles may be contained within the fluid and thus act as the primary debridging agent; alternately, an abrasive tip may be employed (referenced above) as the primary means of debridement (a process commonly known as hydradermabrasion). In the latter, either gas or liquid may be employed to assist in removing debrided skin cells and body fluids and deposit those into a waste receptacle. If liquid is used, those liquids may provide assistive functions including cleaning the treatment area and delivering therapeutic, analgesic, and/or anti-inflammatory agents to the treatment area to facilitate healing, collagen production, reduction of inflammation and other useful benefits.

VIII. OVERVIEW OF THE '607 PATENT

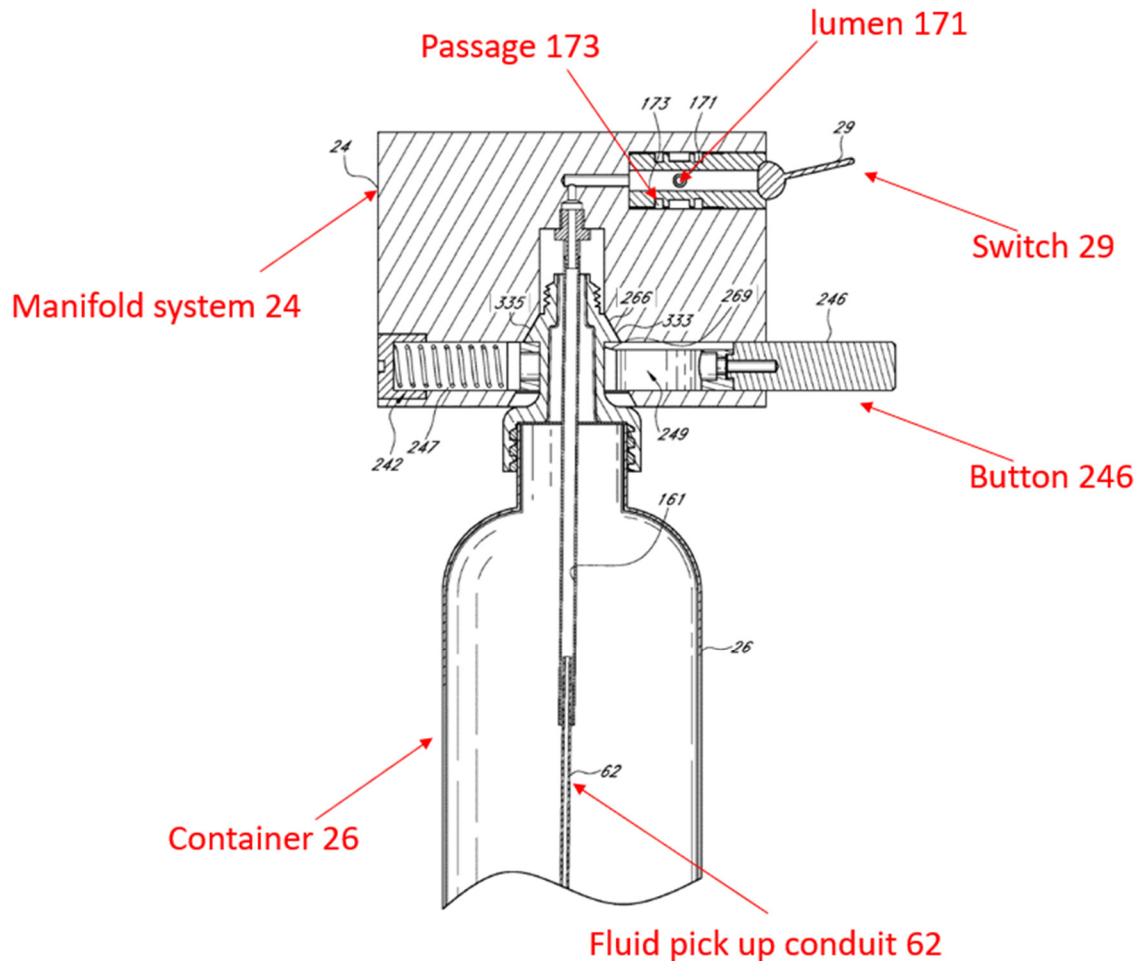
38. The '607 patent relates to an apparatus for treating skin that has a console with a user input device and a handpiece assembly, where the console is coupled to a manifold system “configured to hold releasably a plurality of fluid sources and deliver fluid from at least one of the plurality of fluid sources to the handpiece assembly.” EUNSUNG-1001, Abstract. FIG. 1 of the '607 patent is representative.



'607 patent, FIG. 1 (annotated)

39. As shown in FIG. 1, the console 12 comprises four casters 33 to allow for easy movement. EUNSUNG-1001, 6:13-15. Containers 26 can be releasably coupled to the manifold system 24, which can deliver treatment material from the containers 26 to the handpiece assembly 18 through the line 20. EUNSUNG-1001, 6:21-27.

40. As shown in FIG. 1, the console 12 comprises the manifold system 24 designed to draw treatment fluid from at least one of the containers 26 based on user selection. EUNSUNG-1001, 17:17-19. The manifold system 24 includes switches 29 (one switch 29 for each container 26), which can be used to turn off/on to permit or prevent fluid flow from the bottles 26. EUNSUNG-1001, 17:19-29.



EUNSUNG-1001, FIG. 15C (annotated)

41. The structure of the manifold 24 is further illustrated in FIG. 15B. As shown in FIG. 15B below, container 26 is fluidly connected to the manifold system 24 via fluid pick up conduit 62. EUNSUNG-1001, 18:6-18. The fluid from container 26 can “flow through to and through the lumen 171 towards the line 20” and if the switch 29 is off, “the fluid from one or more of the upstream bottles can flow along the passage 173.” *Id.* In this way, the user can control which container 26 is connected to tube 20 (and handpiece 18) via switch 29 (and similar switches

for each of the upstream containers). *Id.*

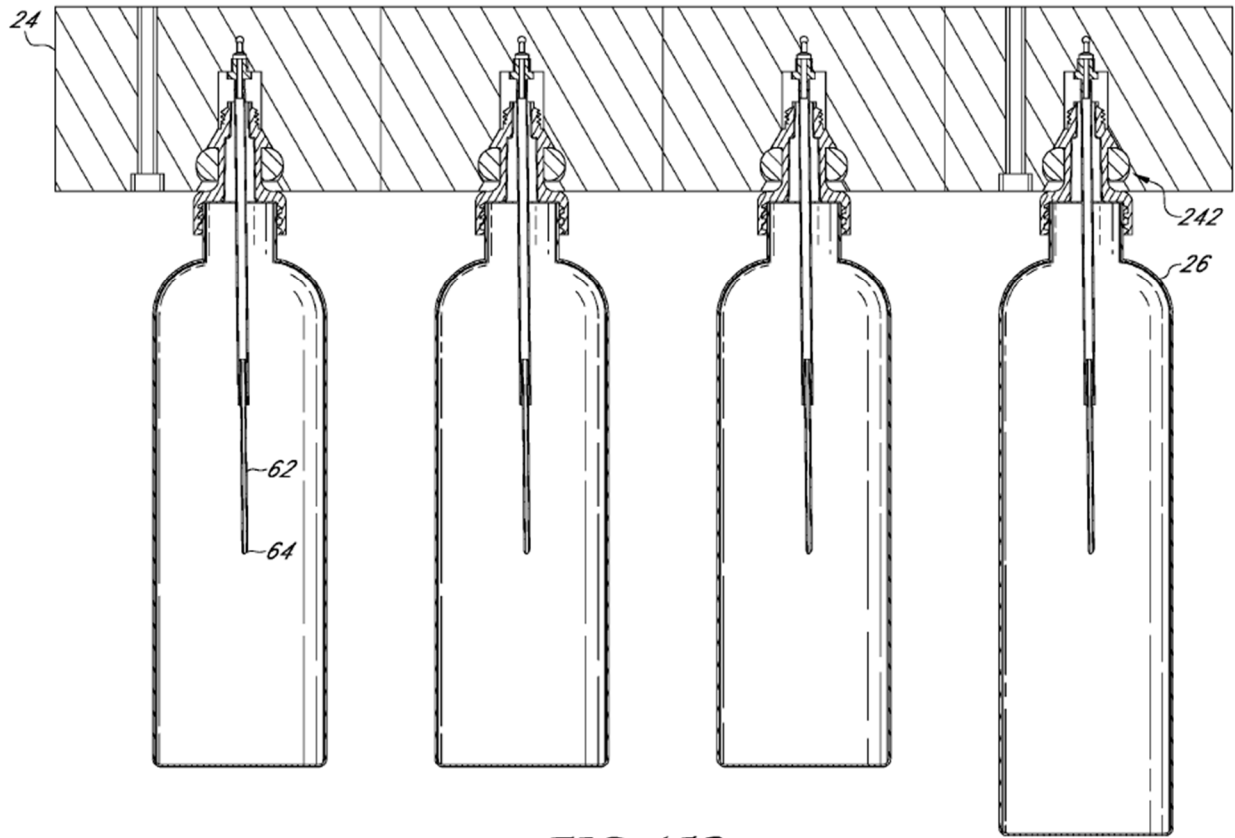


FIG. 15B

EUNSUNG-1001, FIG. 15B

42. Once fluid is actuated into line 20, the fluid is conducted to handpiece 18 where it is delivered to the subject's skin. Abrasion of the skin is achieved through an abrasive pad 128 positioned at the working end of the handpiece. Alternately, geometric members of the handpiece tip 124 may provide an abrasive action to the skin. The "treatment material" which comprises the fluid delivered to the treatment site (skin 80) includes but is not limited to, "... 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.” EUNSUNG-1001, 5:50-52.

43. The actuating force for the delivery of the treatment material is negative pressure, aka vacuum: “A vacuum can be applied by the handpiece assembly 18. For example, the console 12 can have a pump that applies a vacuum via the output line 52. The negative pressure draws waste material... out of the handpiece assembly 18.” EUNSUNG-1001, 11:4-8. The use of positive pressure to actuate fluid flow is not stated in the ’607 patent.

IX. OVERVIEW OF THE PROSECUTION HISTORY

44. The ’607 patent was filed on October 16, 2023, as application No. 18/094,884, claiming priority to, among other things, provisional application No. 60/755,310, filed on December 30, 2005. EUNSUNG-1001, 1:5-27.

45. During prosecution, the Examiner rejected then-pending claims 17-22, 23, 26-27, 32, and 37 for double-patenting; rejected then-pending claims 27-30 as obvious over US2001/0049511A1 (“Coleman”) in view of US 6,162,232 (“Shadduck”); rejected then pending claims 34-36 as obvious over Coleman, Shadduck, and US2003/0018252A1 (“Duchon”). EUNSUNG-1002, 166-179. The Examiner indicated that then-pending claims 17-26 and 37 would be allowable if a terminal disclaimer was filed and that then-pending claim 32 would be allowable if rewritten in independent form. *Id.*, 179-182.

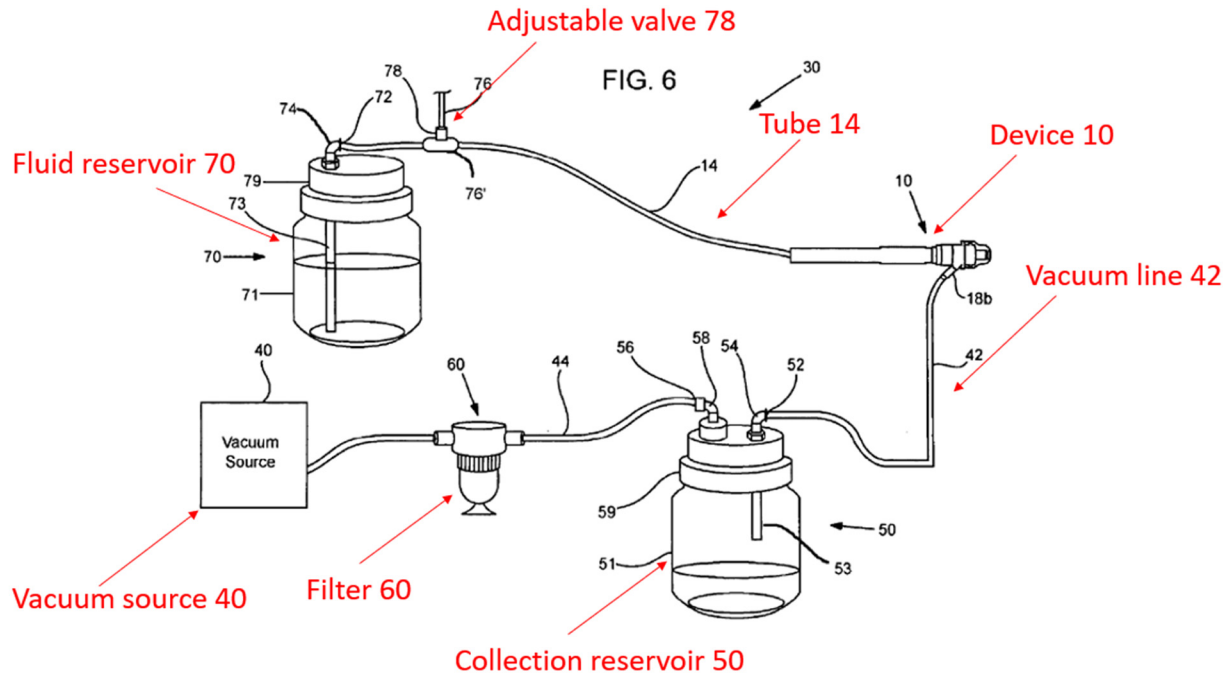
46. In response, Applicant filed a terminal disclaimer, cancelled claim 32, and amended claim 27 to incorporate the subject matter deemed allowable in claim 32 to recite, among other things, “a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal *and that draws treatment material from either the first container or the second container to the handpiece when the tip is placed against skin.*” EUNSUNG-1002, 133-139. These amendments led to allowance. *Id.*, 20-21.

47. During prosecution, the examiner did not consider Palmer or Trueba. Karasiuk, Greenberg, and Waldron were buried in an IDS containing more than 1,200 references. EUNSUNG-1002, 294, 311, 603, 620.

X. SUMMARY OF THE PRIOR ART

1. Karasiuk Overview

48. Similar to the '607 patent, Karasiuk describes a system for conducting microdermabrasion procedures using a handpiece which is in fluid communication with a reservoir. EUNSUNG-1004, Abstract, [0044]-[0045], FIG. 6. The handpiece is configured to both deliver and retrieve a fluid treatment solution to a targeted area of skin. *Id.*, [0063]-[0066].



Karasiuk, FIG. 6 (annotated)

49. As shown in FIG. 6, Karasiuk's system includes a handpiece 10 (also referred to as "device 10" in Karasiuk), a vacuum source 40, and a fluid reservoir 70. EUNSUNG-1004, [0056], FIG. 6. Handpiece 10 is connected to collection reservoir 50 and vacuum source 40 by vacuum line 42. EUNSUNG-1004, [0056], FIG. 6. Handpiece 10 is also connected to fluid container 70 via tube 14. EUNSUNG-1004, [0059], FIG. 6.

50. In operation, "device 10 is positioned so as to place tip 20 in contact with the skin surface to be micro abraded and the vacuum source is turned on to establish a vacuum within the system 30." EUNSUNG-1004, [0063], FIG. 6. "Upon forming the vacuum loop as described above, the fluid contents in fluid reservoir 70 are drawn through tube 14 and into device 10 where they flow out of

the cannula 16 through openings 16d and are applied to the skin.” EUNSUNG-1004, [0064], FIG. 6. “As the flow of the fluids continues out of the vacuum head base and into vacuum line 42, it carries with it the exfoliated skin particles and any other waste that is removed through the microdermabrasion process.” EUNSUNG-1004, [0066], FIG. 6.

51. While showing only one fluid reservoir 70 in FIG. 6, Karasiuk recognizes the desirability of using multiple types of treatment solutions during microdermabrasion. EUNSUNG-1004, [0024] (“other solutions or compounds offering various benefit(s).”) [0047] (“application of lotions/vitamins or other fluids”), [0061] (listing various treatment solutions). Specifically, Karasiuk discloses:

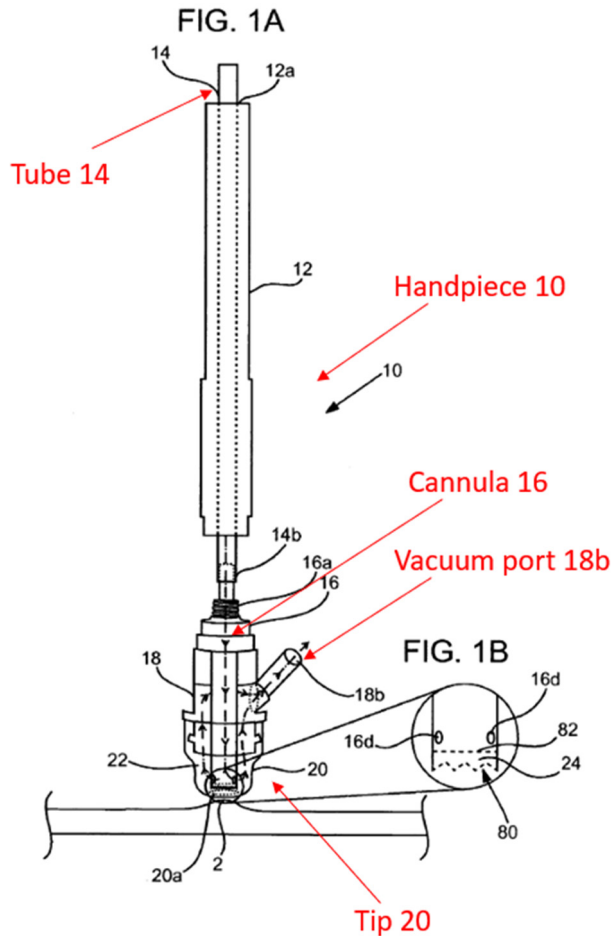
Reservoir 70 may contain solution or a suspension for purposes other than abrasion or pure abrasiveness. General examples, types and/or categories of compounds that may be employed include: bleaching formulations (e.g., 2-4% hydroquinone, 2% Kojic Acid, 1% Vitamin K, and 1% Hydrocortisone in a aqueous base); acne treatment formulations (e.g., Salicylic Acid, alcohol base buffered by witch hazel, etc.); fine lines/wrinkle treatment formulations (e.g., Hyaluronic acid in an aqueous base); hydrating formulations (e.g., Calendula, vitamins A, D and/or E in a mineral oil base); antioxidant formulations/free radical scavengers (e.g., vitamins A, E and K in a mineral oil base). Other examples of product categories that may be employed alone or in combination with other compounds include, antiseptics, astringents, cleansers, pore decongestants, balms, botanicals, collagen stimulators, herbs, microemulsifiers, oxygen delivery vehicles, proteins, serums, skin firming agents, toners, topical anesthetics, and tyrosinase inhibitors. Individually named products as may be used (with associated benefit indicated

parenthetically) include: Aloe Vera (calming); alpha hydroxy acids (peel); alphasalicylic acid (antioxidant); benzoyl and other peroxides (acne); ceramide (hydrator); copper (toning); copper peptide (toning); CoQ-10 (coenzyme Q-10) and other enzymes (toning); cortisone (calming); glycolic acids (peel); hyaluronic acid (collagen stimulation); hydrolipids (hydrator); hydroquinones (bleaching); lactic acids (peel); magnesium ascorbic phosphate (free radical scavenger, collagen stimulator, bleaching); niacin (vascular dilation); phospholipids (moisturization); potassium (toning, psoriasis), and salicylic acids (acne). Of course, any combination of such elements may be provided--even in connection with abrasive particles.

EUNSUNG-1004, [0061].

52. Karasiuk appreciates that “various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention.” EUNSUNG-1004, [0070].

53. Karasiuk discloses: “Upon forming the vacuum loop as described above, the fluid contents in fluid reservoir 70 are drawn through tube 14 and into device 10 where they flow out of the cannula 16 through openings 16d and are applied to the skin.” EUNSUNG-1004, [0064], FIGS. 1A-1B. Karasiuk further illustrates the structure of hand-held device 10 in FIGS. 1A-1B.



Karasiuk, FIGS. 1A-1B (annotated)

54. As shown in FIGS. 1A-1B, the distal end 14b of tube 14 is connected to cannula 16, which is adapted to be fixed to handle 12 and runs through the center of the handpiece. EUNSUNG-1004, [0045]. A treatment tip 20 (fitted over the end of vacuum head based 18) is smooth surfaced and adapted to glide over the skin surface for application of lotions/vitamins or other fluids thereto through an opening 20a. EUNSUNG-1004, [0047]. Cannula 16 mate with vacuum head base 18 to form an annulus 22 therebetween. EUNSUNG-1004, [0048]. A passageway

16c runs the full length of cannula 15 and forms a continuation of the flow path defined by tube 14, ending in the distal end at an abrasive member 24.

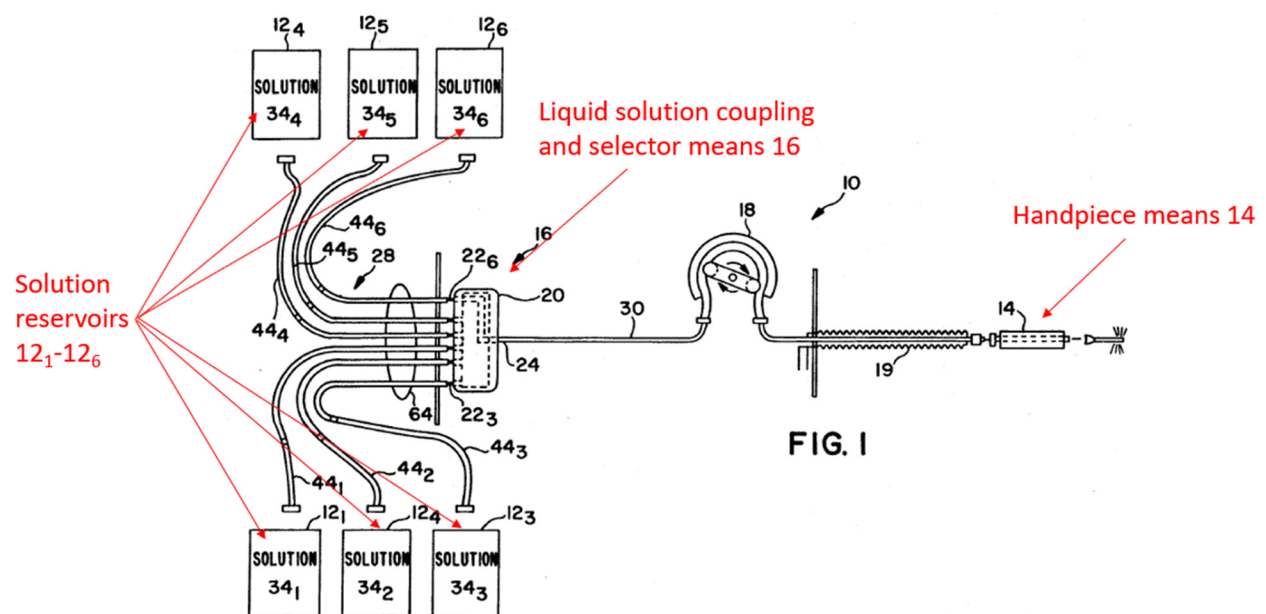
EUNSUNG-1004, [0048]. One or more openings 16d are provided through the wall of the distal tubular structure of cannula 16 to establish one or more flow pathways between passageway 16c and annulus 22. EUNSUNG-1004, [0053].

55. A vacuum port 18b is provided in vacuum head base 18 for connection of a vacuum source, which applies vacuum when opening 20a of tip 20 is sealed off by placing it up against the skin, forming a closed loop vacuum flow path. EUNSUNG-1004, [0054]. This flow path is shown in FIG. 1A. *Id.* As shown, the vacuum draws the treatment material to sequentially flow through tube 14, passageway 16c, opening(s) 16d, annulus 22, tip 20, and vacuum opening 18b. *Id.*; FIG. 1A. Upon forming this vacuum loop, the fluid contents in fluid reservoir 70 are drawn through tube 14 and into device 10 where they flow out of the cannula 16 through openings 16d and are applied to the skin. EUNSUNG-1004, [0064]. As the flow of the fluids continues out of tip 20, vacuum head base 18, and into vacuum line 42, it carries with it the exfoliated skin particles and any other waste that is removed through the microdermabrasion process. EUNSUNG-1004, [0066]. Tip 20 can be (1) tightly fitted over the end of vacuum head base 18, or (2) integrally machined or molded with vacuum head base 18. EUNSUNG-1004, [0047], FIG. 1A

2. Palmer Overview

56. Similar to the '607 patent and Karasiuk, Palmer, titled "Irrigation System and Method for Delivering a Selected One of Multiple Liquid Solutions to a Treatment Site," discloses a medical device system for delivering a selected medical treatment solution to an application site through a handpiece.

EUNSUNG-1005, Abstract, 4:50-68, FIG. 1.



Palmer, FIG. 1 (annotated)

57. As shown in FIG. 1, Palmer's system comprises a handpiece means 14 in fluid communication with a plurality of solution reservoirs 12 (six shown) and a selector means 16 for selecting the fluid container. EUNSUNG-1005, Abstract, 4:50-68, FIG. 1.

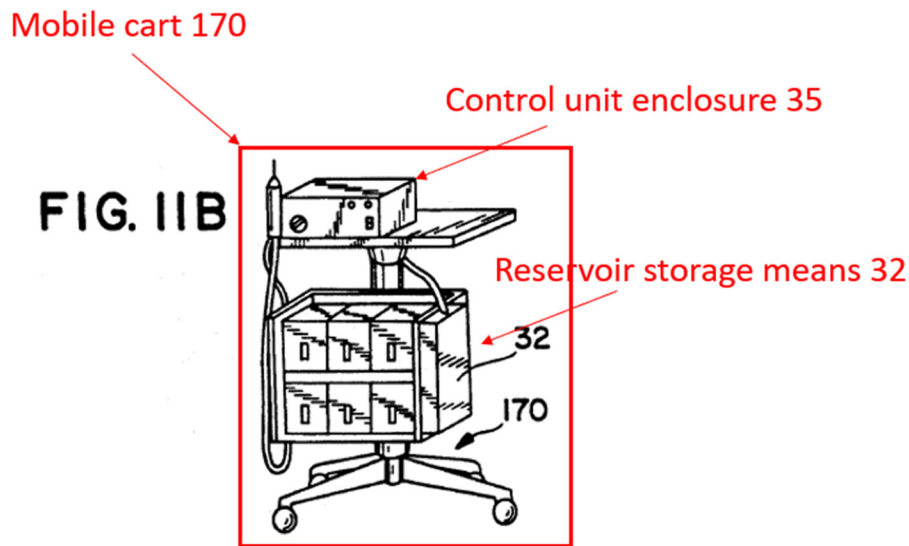
58. Similar to the '607 patent, Palmer also discloses "the reservoir storage means 32 in the form of modular single-shelf racks" for increased portability

and/or organization. EUNSUNG-1005, 9:58-10:16 (“a high degree of flexibility”),

FIGS. 11A (“countertop 168”), 11B (“mobile cart 170”), 11C (“cabinet 172

underneath a counter”); As shown in FIG. 11B below, for example, Palmer’s

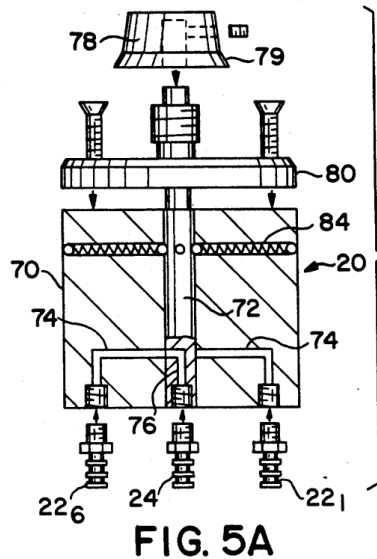
“mobile cart 170” includes the control unit enclosure 35 and the reservoir storage means 32.



Palmer, FIG. 11B (annotated)

59. Palmer also discloses “selector valve means 20 comprises a main body 70 having a central cylinder core or stem 72 rotatably mounted therein. Six liquid inlet passages 74 are formed through the body 70, each inlet passage opening into a respective input port 22 at its outer end, and at its inner end, into the bore which receives the rotatable core 72 in a plane common with the inner ends of the other inlet passages 74. EUNSUNG-1005, 8:6-14. A liquid outlet passage 76 is formed in the rotatable core 72”. *Id.* Selector valve means 20 is directly analogous

to the manifold system of the '607 patent, having fluidic input and output, valving, switching, and manifolding functionalities. Both manually-switched rotary fluidic valves (Palmer) and fluidic block manifold structures (the '607 patent) were well known fluidics components by the Critical Date.



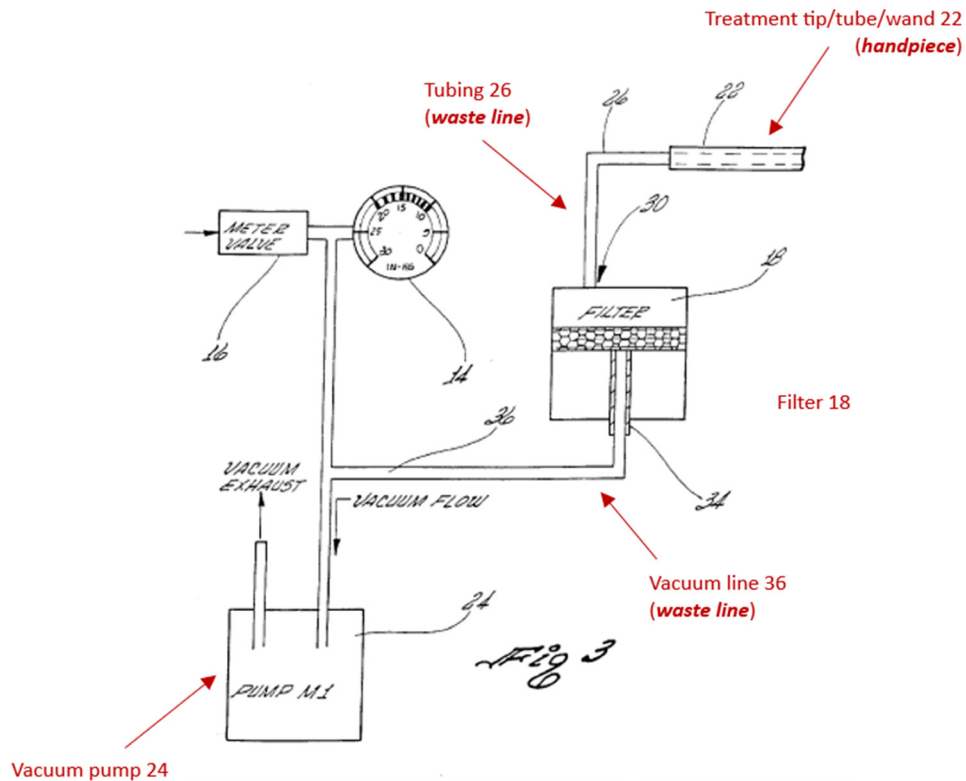
Palmer, FIG. 5A

3. Waldron Overview

60. Similar to Karasiuk and Palmer, Waldron relates to “[a] treatment tool and tissue collection system.” EUNSUNG-1033, Abstract. Specifically, Waldron describes a “device for microdermabrasion,” in which an “abrasive coated tip is moved over the skin surface while a vacuum is applied through the tube to the skin surface to remove cells abraded from the skin surface.” *Id.*, 2:47-52.

61. Waldron’s system, illustrated below in FIG. 3, includes “treatment tip 22” (also referred to as “tube 22” or “wand 22”) that is connected to “vacuum

pump 24” through “tubing 26,” “filter 18,” and “vacuum line 36.” *Id.*, 3:54-4:7.



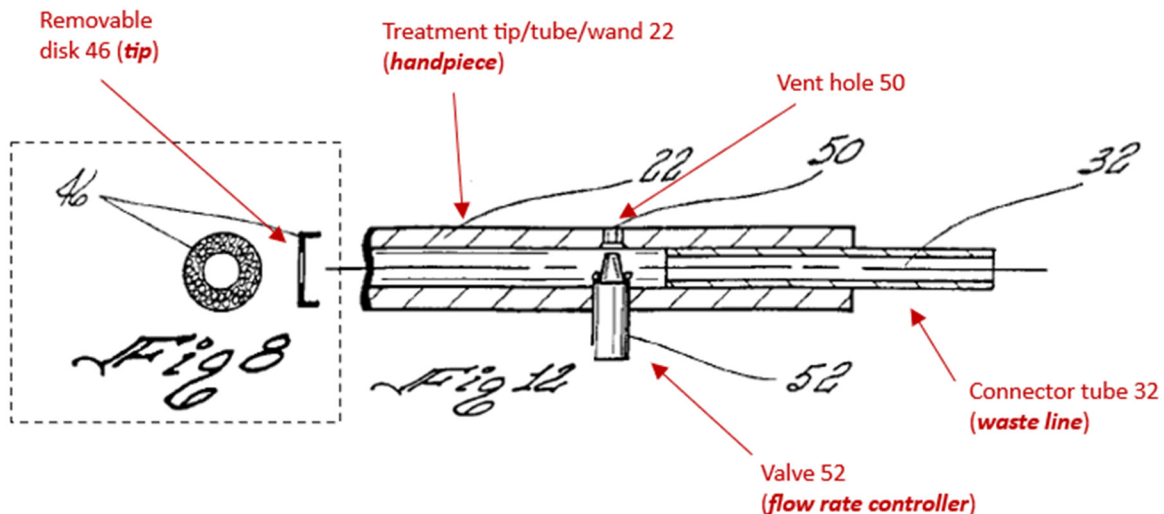
Waldron, FIG. 3 (annotated)

62. Waldron discloses several different embodiments of treatment tip 22. EUNSUNG-1033, 4:38-6:36; FIGS. 4-18. For example, the treatment tip may be a solid stainless steel tube with a diamond coated end. *Id.*, 4:66-5:4. In other words, treatment tip/tube/wand 22 includes an integrated abrasive end, and the entire “tool can be steam or chemical sterilized between uses.” *Id.*, 4:66-5:4; *see, e.g., id.*, FIGS. 4-5, 10-13.

63. Alternatively, the treatment tip “could be a stainless steel, plastic, or other stiff tubular material, with a suitable removable and replaceable tip.”

EUNSUNG-1033, 5:8-12. For example, Waldron's FIG. 8, reproduced below with FIG. 12, depicts "a removable disk 46 sized to fit over the end of the tube 22." *Id.*, 5:13-14. "The disk has an abrasive end or abrasive material attached to the outer end." *Id.*, 5:14-15. And Waldron explains that "[d]uring the procedure[,] various disc with different abrasive characteristics can be interchanged and at the conclusion of the procedure the disc(s) 46 can be discarded." *Id.*, 5:15-18.

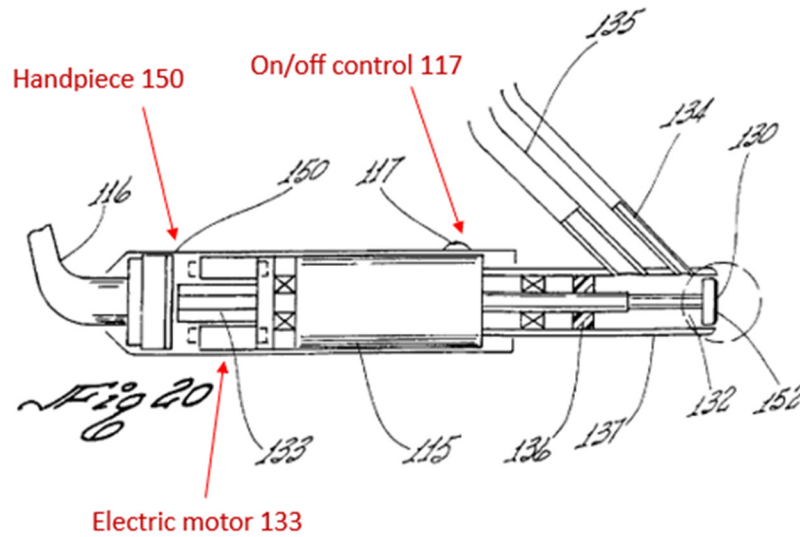
64. A POSITA would have recognized Waldron's treatment tip/tube/wand 22 as the portion of Waldron's device that is held by an operator while pressing the removable abrasive tip against the skin during a microdermabrasion treatment. EUNSUNG-1033, 4:27-37. Thus, a POSITA would have understood Waldron's treatment tip/tube/wand 22 as directly analogous to the claimed handpiece.



Waldron, FIGS. 8 & 12 (annotated)

65. Waldron states that its “device uses a vacuum pump 24 which generates a constant level of vacuum, which is controlled (lessened) by the venting of air into the system by the valve 16.” EUNSUNG-1033, 5:41-44. Waldron discloses an alternative arrangement, depicted above in FIG. 12, in which “the level of vacuum can [] be decreased by air vented into the system through vent hole 50 by adjusting flow control valve 52 mounted on the wand 22.” *Id.*, 5:44-50. Waldron further states that “valve 52 can be configured to be a simple on/off control or variable so that suction can be readily adjusted by the operator while performing the procedure.” *Id.*, 5:50-52.

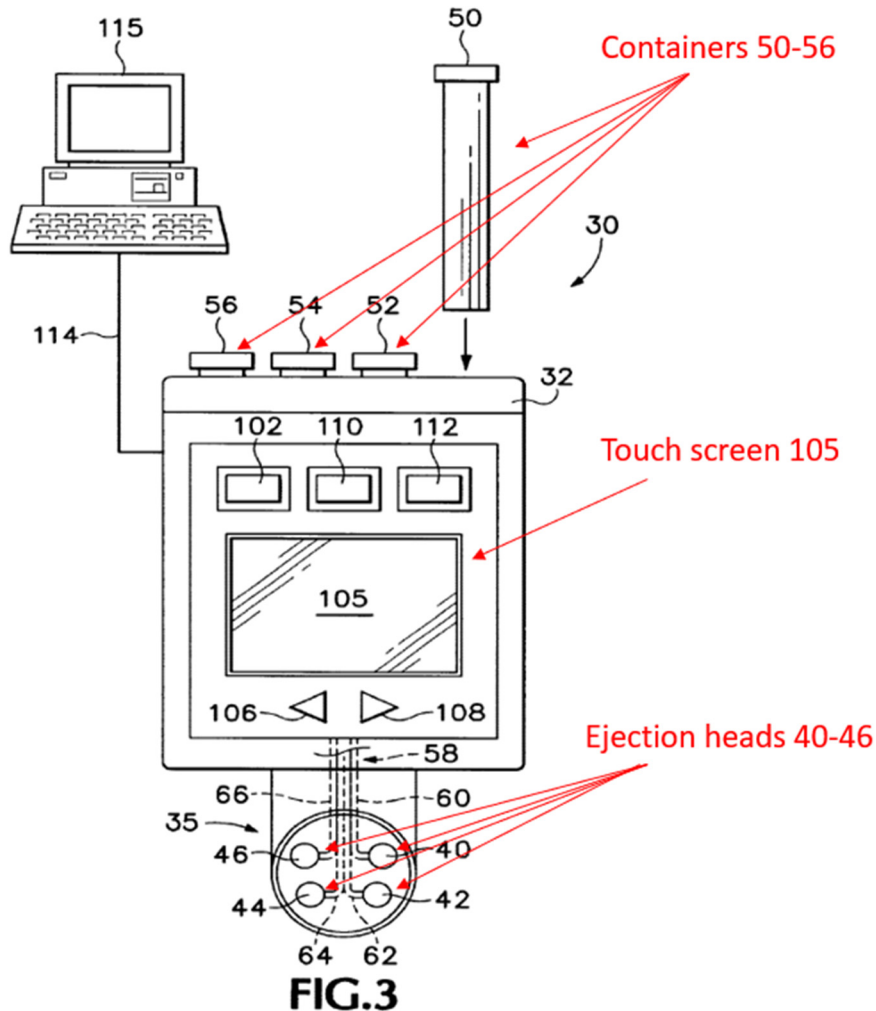
66. In an additional embodiment, Waldron discloses a handpiece with a rotating abrader. EUNSUNG-1033, 6:21-8:7. As depicted below in FIG. 20, handpiece 150 includes electric motor 133 to rotate abrader 132. *Id.*, 7:4-25. Electric motor 133 “is activated by the on/off control 117 mounted on the hand piece.” *Id.* Waldron states that “[a]n alternative is to use a foot pedal (not shown) to turn the motor on and off.” *Id.*



Waldron, FIG. 20 (annotated)

4. Trueba Overview

67. Similar to Karasiuk and Palmer, Trueba discloses a fluid delivery system that includes multiple containers (e.g., Trueba's containers 50-56) and pump means (e.g., Trueba's ejection heads 40-46). EUNSUNG-1008, Abstract, 8:49-11:3, FIG. 3.



Trueba, FIG. 3 (annotated)

68. Trueba's fluid delivery is controlled by a computer (e.g., Trueba's controller 100) linked to a user input (e.g., external computer 115 or touch screen 105): "Controller 100 operates to apply firing signals to the ejection heads 40-46, which respond by ejecting fluid from reservoirs 50-56." EUNSUNG-1008, 10:60-62. Touch screen 105 "may include a series of images that, when touched with a finger or stylus, program the controller 100." EUNSUNG-1008, 11:50-59, FIG. 3. The display screen 105 can be used to "indicate which selections have been made"

and to display “information such as desired dosages, frequency, and potential side effects.” EUNSUNG-1008, 11:42-49, FIG. 3. Further, the touch screen can be operated to select a particular drug or dosage, or to program the controller. EUNSUNG-1008, 11:60-12:8.

69. Trueba discloses: “Multiple compositions can be dispensed simultaneously or sequentially.” EUNSUNG-1008, 11:4-5. For example, corticosteroid from reservoir 52 would be administered to a subject having stable reactive airway disease, but if symptoms persist, then the β -agonist from reservoir 50 also can be delivered (for example, in response to pressing an activation button or programming the applicator).” EUNSUNG-1008, 11:15-20.

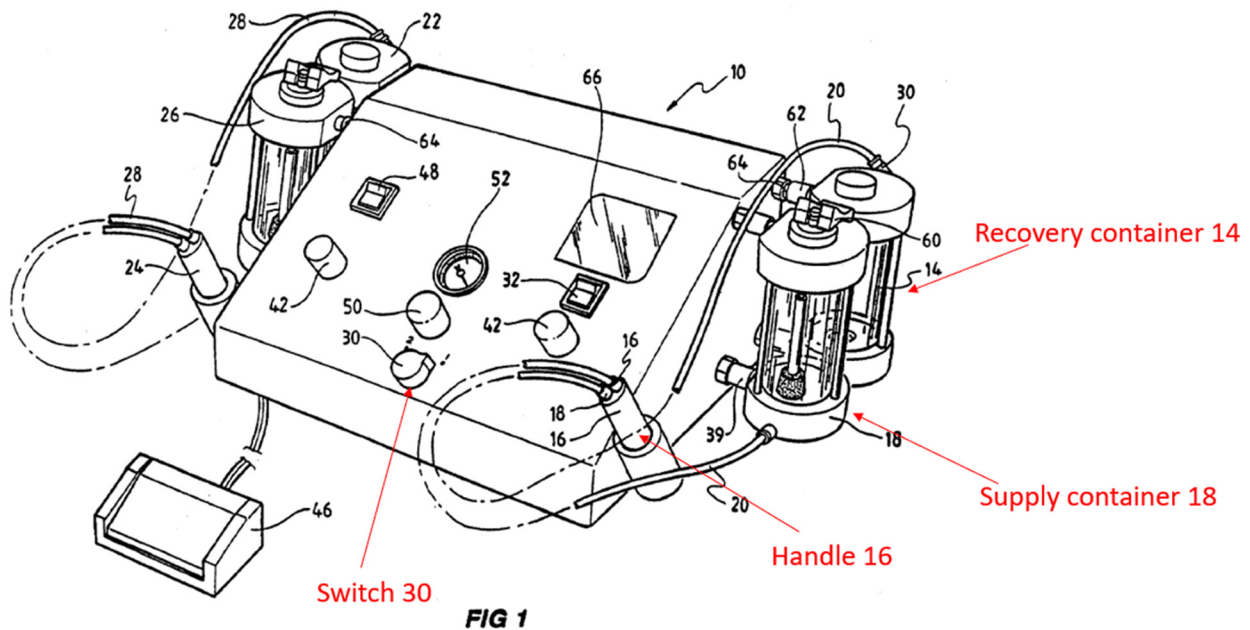
70. Using Trueba’s computer control, multiple compositions can be automatically dispensed simultaneously or sequentially. EUNSUNG-1008, 3:4-8, 5:18-6:9 (“Several modules may contain the same or different bioactive compositions”), 6:10-16 (“may be used to apply the agent to an area of skin for topical application of a bioactive composition”), 11:4-34 (“Multiple compositions can be dispensed simultaneously or sequentially”).

71. Further, the device can be programmed to respond to changing clinical circumstances. EUNSUNG-1008, 11:15-20 (“For example, only the corticosteroid from reservoir 52 would be administered to a subject having stable reactive airway disease. However, if symptoms persist, then the β -agonist from

reservoir 50 also can be delivered.”). Further, the device can be programmed to “prevent unauthorized alteration of dosages” and “permit certain ranges of dosages to be administered.” EUNSUNG-1008, 12:2-9.

5. Greenberg Overview

72. Greenberg describes a system for conducting microdermabrasion procedures using a handpiece (e.g., hand tool 16) to apply treatment materials to a targeted area of skin. EUNSUNG-1006, Abstract, [0049]-[0064], FIG. 1.



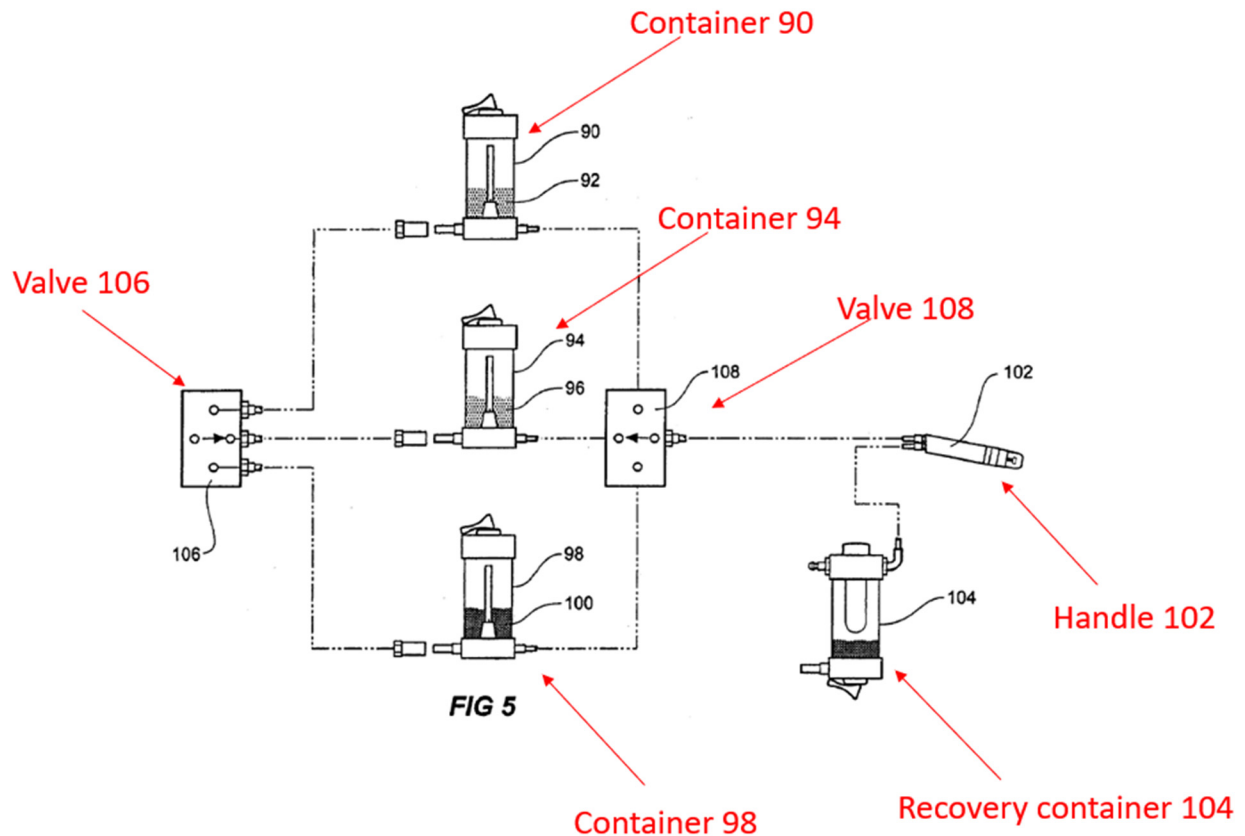
Greenberg, FIG. 1 (annotated)

73. Greenberg discloses that its system comprises: (1) “a pneumatic source operatively connected to a recovery container and to a hand tool”; (2) “a plurality of supply containers including particulates”; (3) “a valve selectively connecting said pneumatic source, recovery container and hand tool to a selected

one of said supply containers.” EUNSUNG-1006, [0013]-[0016]. In operation, “said pneumatic source provides for an air flow through the recovery container, hand tool and the selected supply container in communication with same, drawing said particles from the supply container through the hand tool and into the recovery container, said hand tool positioned on a surface to be treated and including an aperture so located that particles passing through said hand tool are caused to impinge on the surface thereby treating it.” EUNSUNG-1006, [0017], FIG. 3. Greenberg describes “the pneumatic source is a vacuum pump.” EUNSUNG-1006, [0026], [0004], [0049]-[0059], [0066].

74. Greenberg also describes an implementation that provides “a choice of different particles to use in a micro-dermabrasion machine,” which “can be achieved in the present apparatus by having an apparatus with a plurality of supply containers housing different particles” as illustrated in FIG. 5. EUNSUNG-1006, [0073]-[0077]. In FIG. 5, Greenberg’s device comprises three supply containers (e.g., containers 90, 94, and 98), and valves 106 and 108 can control which container is connected to handpiece 102 and recovery container 104. EUNSUNG-1006, [0077], FIG. 5. In operation, “[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 th[e]n connects that supply container to the handle 102 and recovery container

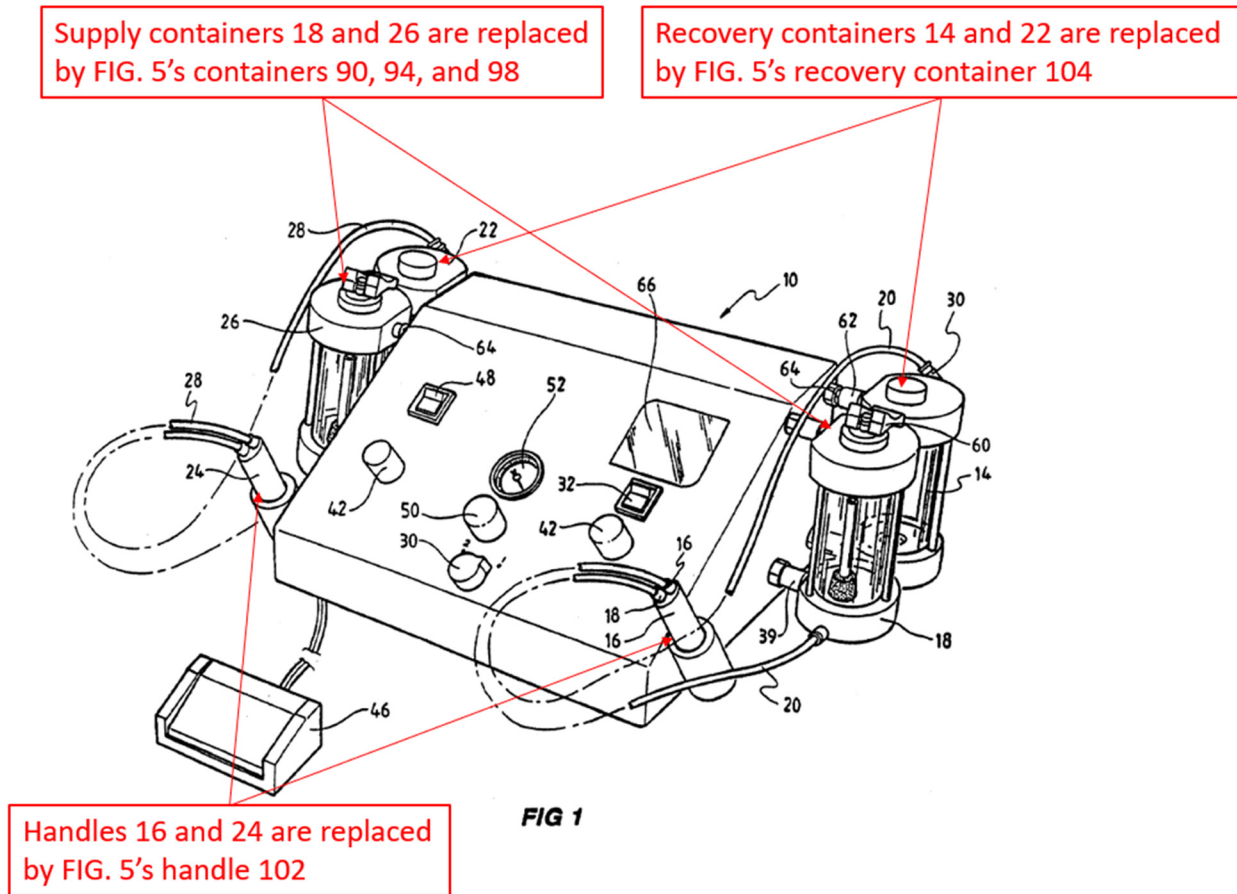
104.” EUNSUNG-1006, [0077], FIG. 5.



Greenberg, FIG. 5 (annotated)

75. A POSITA would have readily appreciated and found it obvious that FIG. 5's structure would have been readily incorporated into FIG. 1's apparatus. EUNSUNG-1006, [0077] ("This can be achieved in **the present apparatus** by having an apparatus with a plurality of supply containers"). In particular, FIG. 5's containers (90, 94, 98) and valves (106, 108) would be used instead of FIG. 1's supply containers 18 and 26, FIG. 5's recovery container 104 would be used instead of FIG. 1's recovery containers 14 and 22, and FIG. 5's single handle 102 replaces FIG. 1's two handles 16 and 24. Moreover, in FIG. 5's implementation, it

would have been obvious to a POSITA to locate valve 106 and 108 in apparatus 10 so that they may interface with, for example, containers 94, 96, and 98. To connect the multiple containers 90, 94, 98 with the single handle 102, FIG. 5's control valves (e.g., valves 106 and 108) are used to enable selective fluid communication with each of the containers. Other structures described with respect to FIGS. 1-4 would have been similarly applicable for the FIG. 5 implementation. For example, the tubing (e.g., tube 20) described in FIG. 1 would have been similarly used for the connection between FIG. 5's valve 108 and handle 102. Further, each of FIG. 5's multiple containers (e.g., containers 90, 94, 98, 104) would have been connected to FIG. 1's console (e.g., apparatus 10) in the same manner as FIG. 1's containers 14, 18, 22, 26. EUNSUNG-1006, [0053], [0062], FIG. 1. Notably, the same mechanism and operation described with respect to FIG. 1 would have been used for FIG. 5's implementation.



Greenberg, FIG. 1 (annotated)

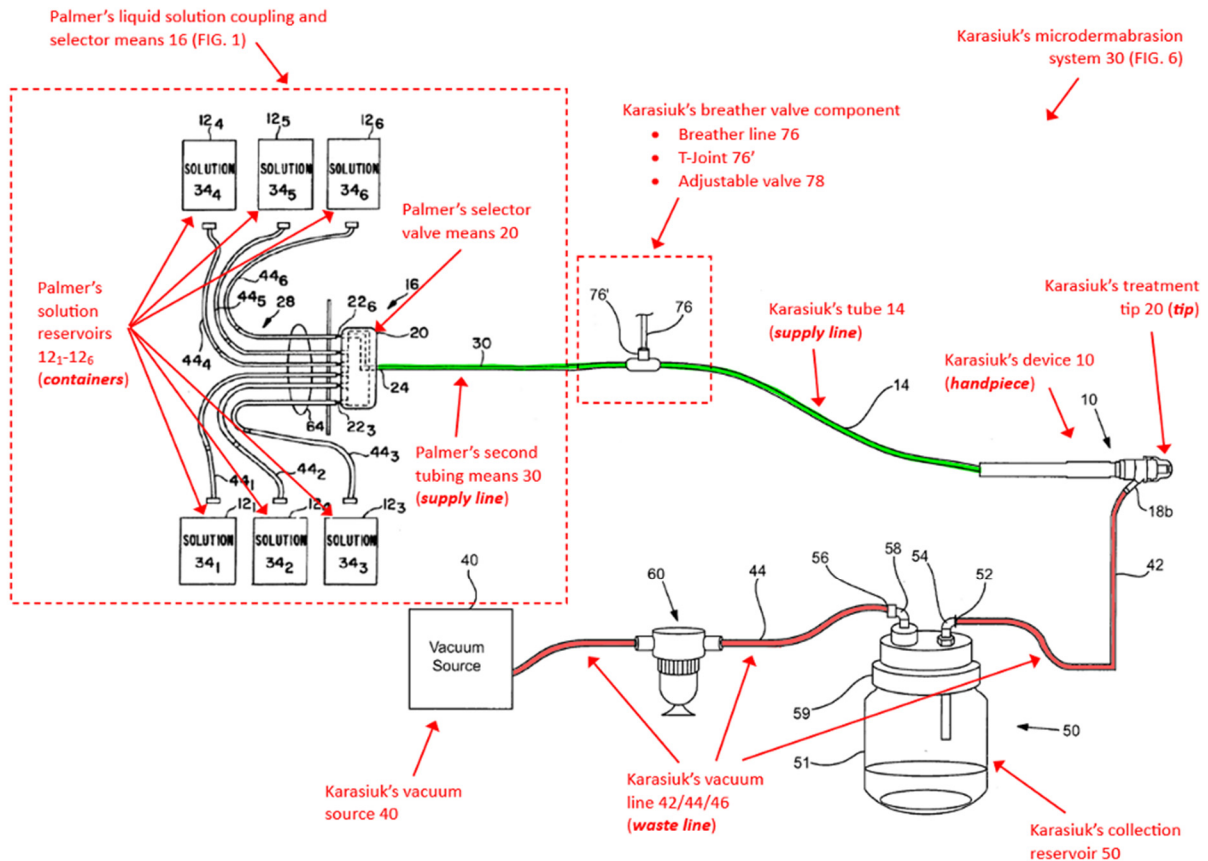
76. Greenberg discloses that “the pneumatic source is a vacuum pump” (EUNSUNG-1006, [0026], [0004], [0049]-[0059], [0066]) and “said pneumatic source provides for an air flow through the recovery container, hand tool and the selected supply container in communication with same, drawing said particles from the supply container through the hand tool and into the recovery container.” EUNSUNG-1006, [0017]. The same mechanism and operation would have been used for FIG. 5’s implementation by, for example, connecting a vacuum source (e.g., vacuum pump 12) to recovery container 104.

77. Of note, Greenberg provides a means of pressure stabilization through the use of valve 106 arranged fluidically upstream from the supply containers 90, 94, and 98. Valve 106 allows selectable valving to the inlets of the containers and thereby provides air flow into the container while fluidized abrasive is exiting the container through valve 108. If valves 106 and 108 are not both open, treatment material will not flow from the container.

XI. [GROUND 1A] – Karasiuk and Palmer

1. The Karasiuk-Palmer Combination

78. It is my opinion that a POSITA would have been motivated to combine Karasiuk and Palmer with a reasonable expectation of success. In the Karasiuk-Palmer combination (“Karasiuk-Palmer”), Karasiuk’s reservoir 70 would have been modified based on Palmer’s teachings of multiple containers (e.g., Palmer’s reservoirs 12₁-12₆) and selector means (Palmer’s selector means 16), an example of which is illustrated in Modified FIG. 6 below.



Modified FIG. 6 of Karasiuk (annotated)

79. Further, Karasiuk's vacuum source would be used to collect debris and pump the treatment fluids from multiple fluid containers (e.g., Palmer's fluid containers) in the combination. Instead of being connected to a single reservoir 70, Karasiuk's tube 72 would replace Palmer's second tubing means 30, or would be connected to the second tubing means 30 or an output from the multiple fluid containers (e.g., Palmer's output 24) to achieve benefits that flow from selection of different treatment solutions. In the resulting system, the vacuum source serves two functions simultaneously: (1) pumping the treatment solution and (2)

removing waste/debris, as described in Karasiuk. EUNSUNG-1004, [0020], [0056], [0064], [0066].

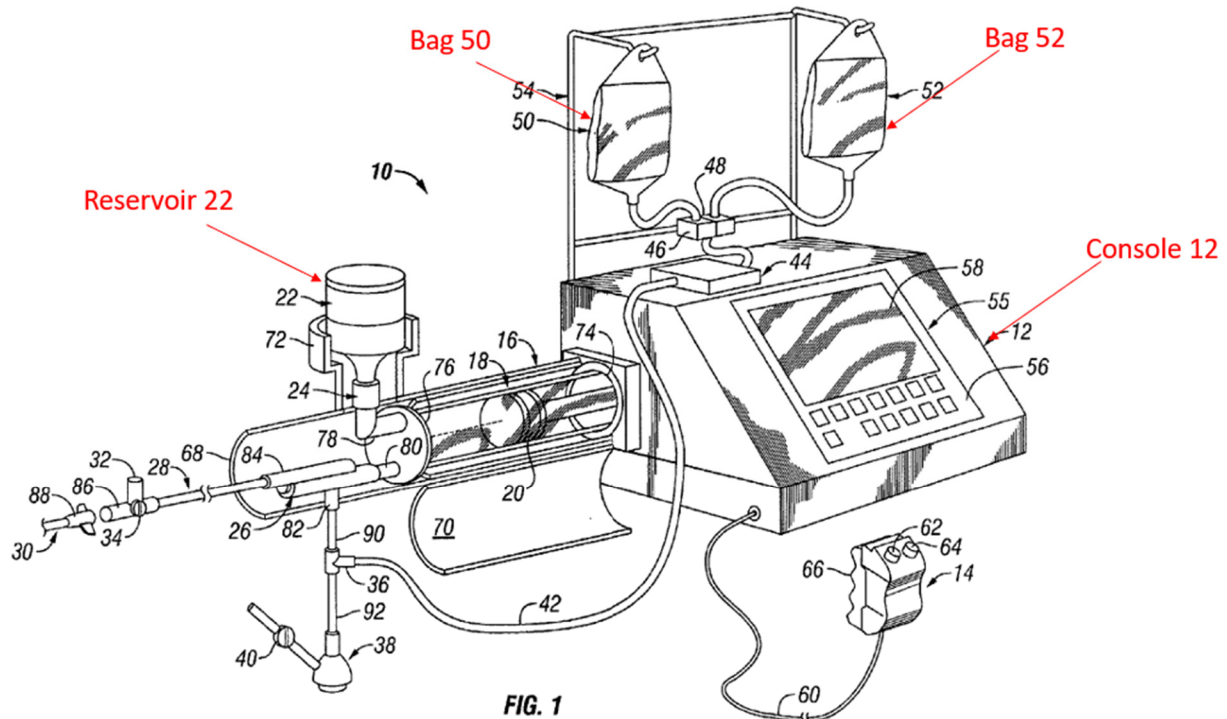
80. In addition to adapting Karasiuk's system to use multiple treatment containers in the Karasiuk-Palmer combination, a POSITA would have been motivated and found it obvious to place both (1) multiple containers and selector means (e.g., Palmer) and (2) handpiece, waste container, filter, and vacuum source (e.g., Karasiuk) in a modular structure for increased portability and/or organization, as taught by Palmer. EUNSUNG-1005, 9:58-10:2. In this regard, Palmer discloses that "[b]y providing the reservoir storage means 32 in the form of modular single-shelf racks, a high degree of flexibility is provided...the reservoir storage means 32 can be placed on a countertop 168 (FIG. 11A), or on a mobile cart 170 (FIG. 11B) or in a cabinet 172 underneath a counter (FIG. 11C)." EUNSUNG-1005, 9:63-10:2, FIGS. 11A-11C. In fact, such modular configuration for medical devices was well-known before the Critical Date. EUNSUNG-1011, EUNSUNG-1006.

81. For example, Duchon discloses a medical fluid delivery system where the user can choose the desired fluid (e.g., contrast material or saline) from multiple fluid containers (e.g., reservoir 22 or bag 50). EUNSUNG-1010, Abstract, FIG. 1, [0006]. Duchon discloses in relevant part:

[0063] **Console 12** houses the electrical controls for system 10, together with the motors which drive piston 20 and peristaltic

pump 44. On the front surface of **console 12**, user interface 55 provides control switches 56 and display 58 through which the user may enter control settings and monitor the operational state of system 10. The console can be free-standing, preferably configured for mounting on a transport cart assembly.

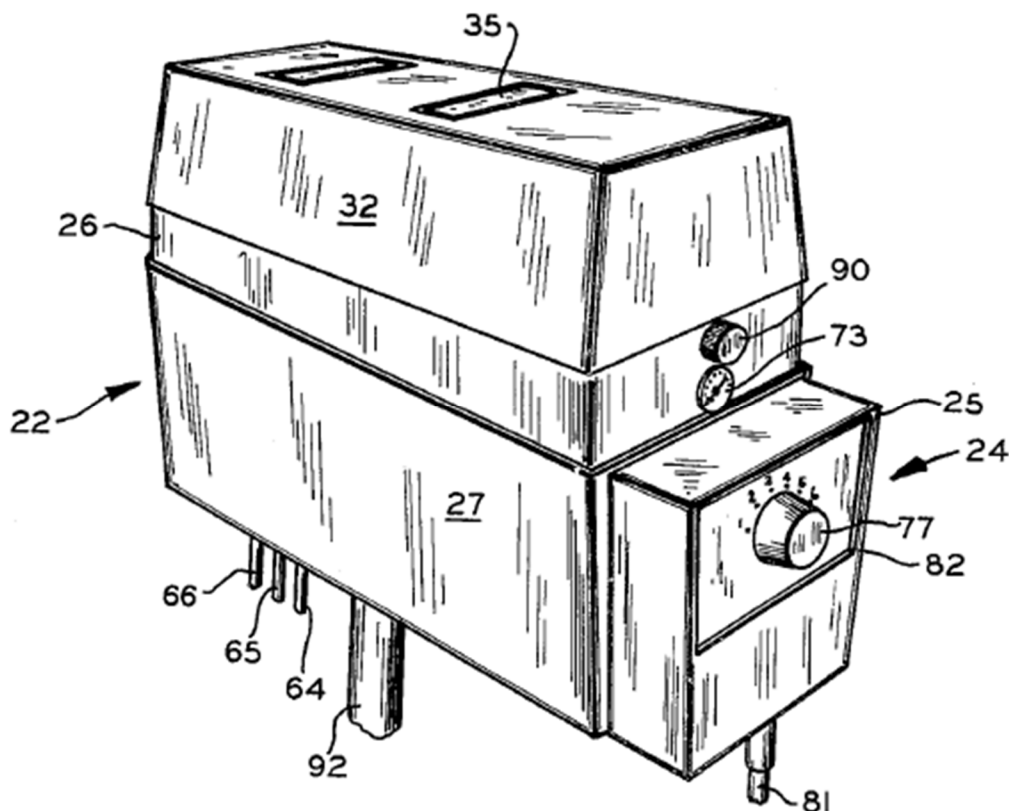
EUNSUNG-1010, [0063].



Duchon, FIG. 1 (annotated)

82. As another example, Armstrong (EUNSUNG-1011) discloses a system 21 comprising (1) a supply station 22 which houses multiple containers (e.g., fluid reservoirs 46) and (2) a control box 82 which houses a selective coupling means 24 (e.g., selector valve 74) to select among the fluid sources.

EUNSUNG-1011, FIG. 2, 4:57-60, 5:55-61.



Armstrong, FIG. 2

83. Similarly, Greenberg (EUNSUNG-1006) discloses a modular apparatus 10 that includes vacuum pump 12 and switch 30 and connects to multiple containers and handle 16. EUNSUNG-1006, FIGS. 1 and 5.

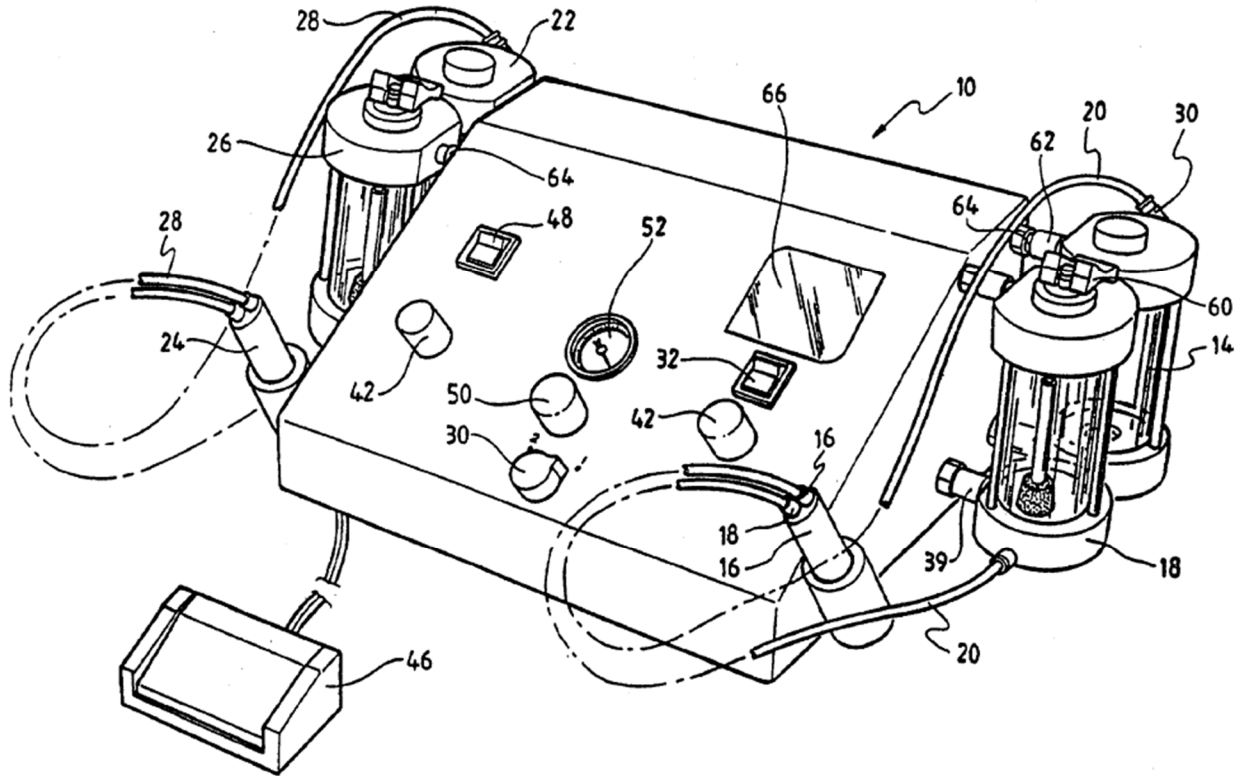
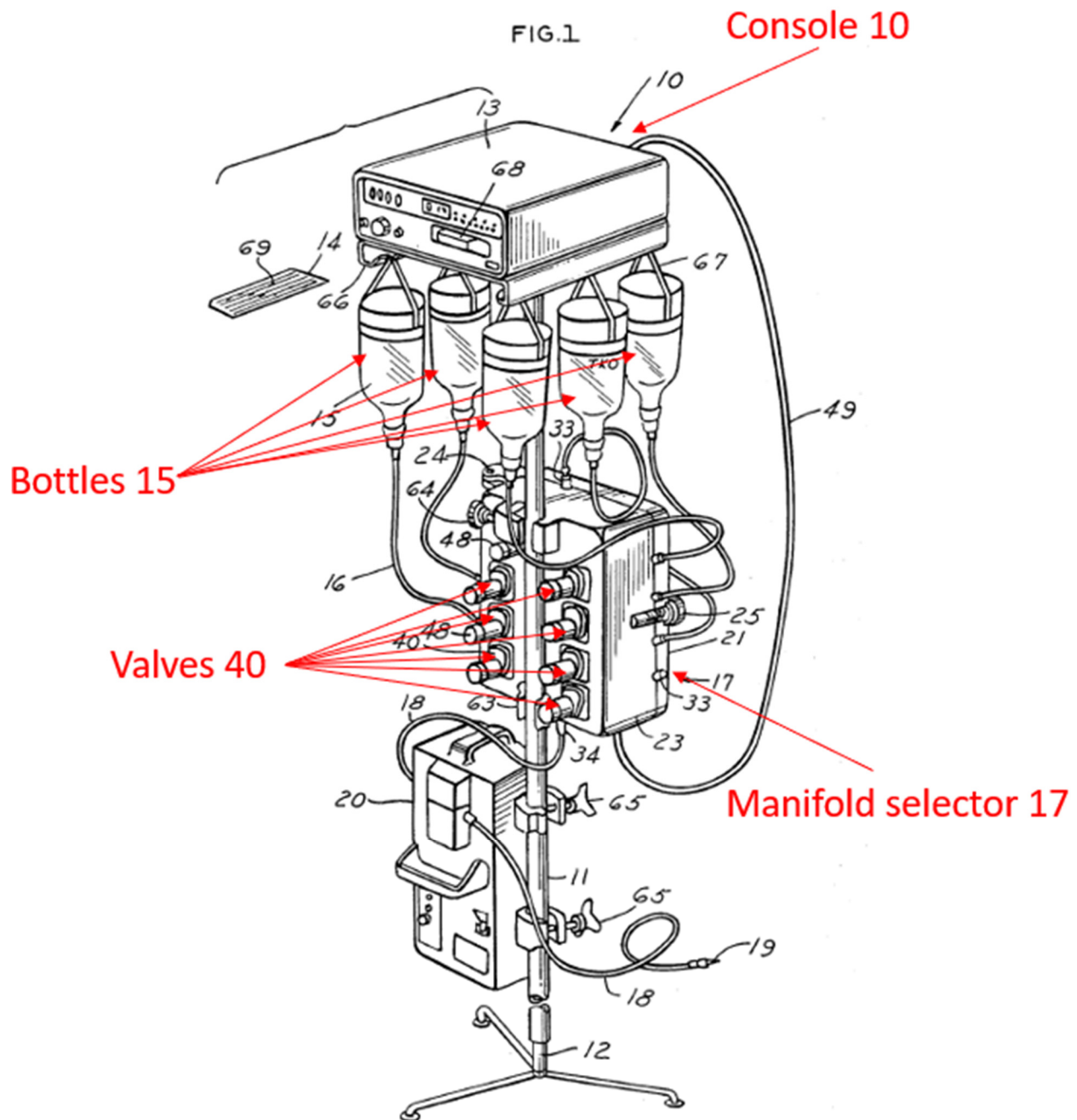


FIG 1

Greenberg, FIG. 1

84. As another example, Wunsch discloses an apparatus (e.g., console 10) for sequentially dispensing a plurality of solutions through a manifold that is connected to each of the solutions to be administered. EUNSUNG-1020, Abstract, 7:39-56, 8:17-26, FIGS. 1-4. As shown in FIG. 1, the manifold selector 17 includes a plurality of valves 40, which control the flow of solution from the plurality of bottles 15. EUNSUNG-1020, 6:18-48, 7:16-56. In operation, the user can program the sequencer timer 13 to automatically operate the valves 40 to achieve automatic switching between different solutions and sequential delivery of different solutions. EUNSUNG-1020, 9:36-10:64.

FIG.1



Wunsch, FIG. 1 (annotated)

85. Several reasons would have prompted a POSITA to modify Karasiuk's system based on Palmer's teachings. As discussed in § X.1, Karasiuk's system uses a handpiece for applying a fluid treatment solution to a treatment site

during microdermabrasion and a vacuum for collecting waste from the microdermabrasion procedure. EUNSUNG-1004, Abstract, [0044]-[0045], [0056], [0059], [0063]-[0066], FIG. 6. Karasiuk recognizes the desirability of using multiple types of treatment solutions during microdermabrasion. EUNSUNG-1004, [0024] (“other solutions or compounds offering various benefit(s).”), [0047] (“application of lotions/vitamins or other fluids”), [0061] (listing various treatment solutions). Specifically, Karasiuk discloses:

Reservoir 70 may contain solution or a suspension for purposes other than abrasion or pure abrasiveness. General examples, types and/or categories of compounds that may be employed include: beaching formulations (e.g., 2-4% hydroquinone, 2% Kojic Acid, 1% Vitamin K, and 1% Hydrocortisone in a aqueous base); acne treatment formulations (e.g., Salycilic Acid, alcohol base buffered by witch hazel, etc.).fine lines/wrinkle treatment formulations (e.g.,: Hyaluronic acid is an aqueous base); hydrating formulations (e.g., Calendula, vitamins A, D and/or E in a mineral oil base); antioxidant formulations/free radical scavengers (e.g., vitamins A, E and K in a mineral oil base). Other examples of product categories that may be employed alone or in combination with other compounds include, antiseptics, astringents, cleansers, pore decongestants, balms, botanicals, collagen stimulators, herbs, microemulsifiers, oxygen delivery vehicles, proteins, serums, skin firming agents, toners, topical anesthetics, and tyrosinase inhibitors. Individually named products as may be used (with associated benefit indicated parenthetically) include: Aloe Vera (calming); alpha hydroxy acids (peel); alphasalicylic acid (antioxidant); benzoyl and other peroxides (acne); ceramide (hydrator); copper (toning); copper peptide (toning); CoQ-10 (coenzyme Q-10) and other enzymes (toning); cortisone (calming); glycolic acids (peel); hyaluronic acid (collagen stimulation); hydrolipids (hydrator); hydroquinones (bleaching); lactic acids (peel); magnesium ascorbic phosphate (free radical scavenger, collagen stimulator,

bleaching); niacin (vascular dilation); phospholipids (moisturization); potassium (toning, psoriasis), and salicylic acids (acne). Of course, any combination of such elements may be provided--even in connection with abrasive particles.

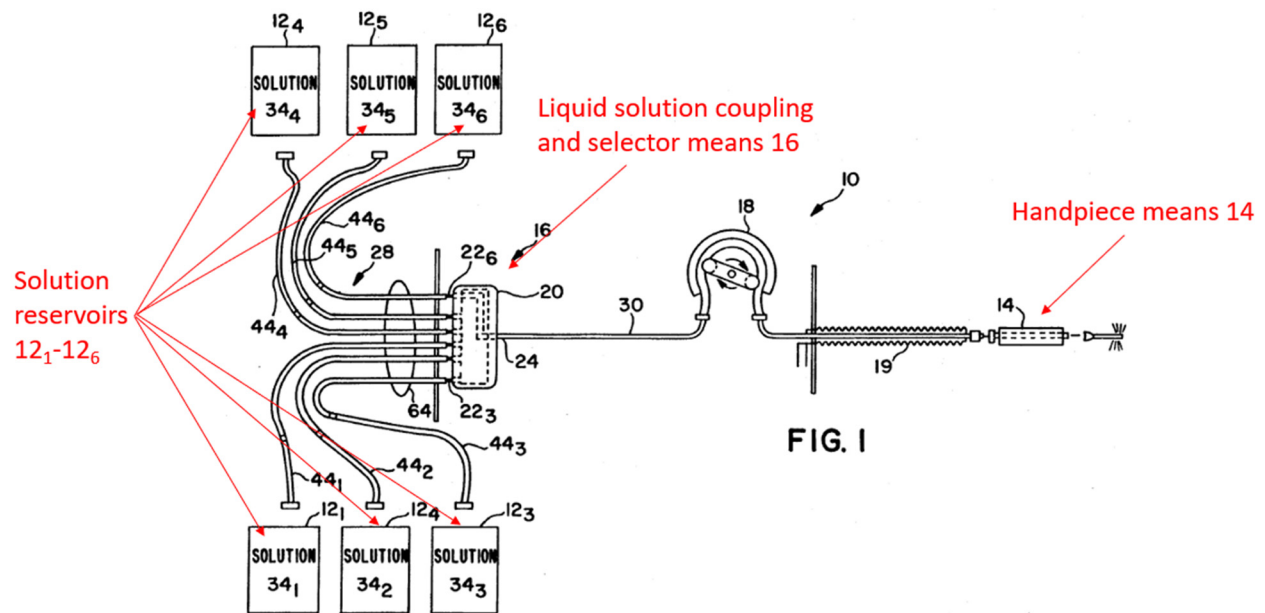
EUNSUNG-1004, [0061].

86. Based on general knowledge in the field, a POSITA would have understood that multiple treatment solutions are desirable during microdermabrasion. For example, Lee discloses delivering vitamin C during microdermabrasion to confer various benefits including inhibition of melanogenesis, promotion of collagen biosynthesis, prevention of free radical formation, and acceleration of wound healing. EUNSUNG-1016, 1. Further, Burgess discloses that when microdermabrasion is completed, a moisturizer with adequate sunscreen is applied. EUNSUNG-1013, 86. This is because microdermabrasion partially removes the protective barrier of the skin and extra protection is needed.

87. Further, Karasiuk appreciates that “various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention.” EUNSUNG-1004, [0070]. From this disclosure and a POSITA’s general knowledge, a POSITA would have been motivated to consider the use of multiple containers of treatment solutions to improve the flexibility and functionality offered by Karasiuk’s system. Indeed, the fluid delivery techniques using multiple containers of treatment solutions with Karasiuk’s handpiece were

well-known and part of a POSITA's general knowledge by the Critical Date.

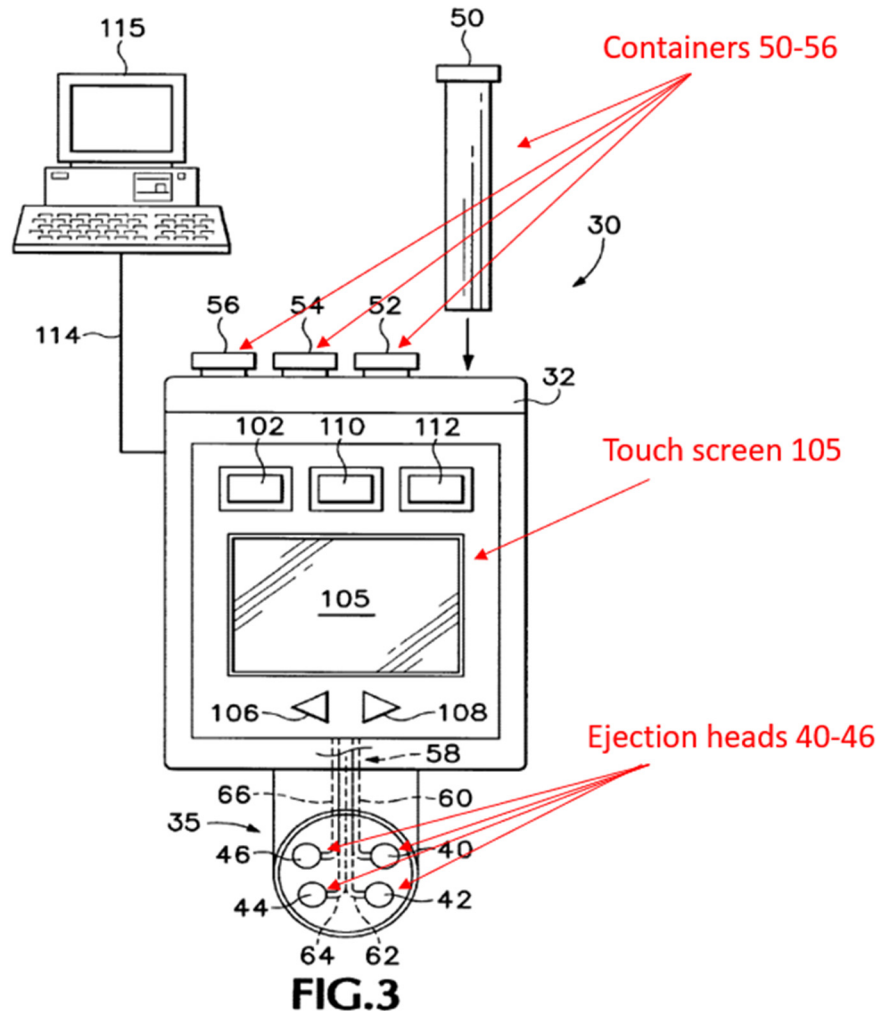
EUNSUNG-1005, Abstract, FIG. 1, 2:48-51, claim 1; EUNSUNG-1008, FIG. 3, 3:23-26, 11:4-34; EUNSUNG-1007, FIG. 2, 1:60-63, claim 1; EUNSUNG-1011, Abstract, FIG. 1, 2:29-49, claim 1; EUNSUNG-1020, Abstract, 7:39-56, 8:17-26, FIGS. 1-4. For example, Palmer discloses a medical device system for delivering a selected medical treatment solution to an application site through a handpiece.



Palmer, FIG. 1 (annotated)

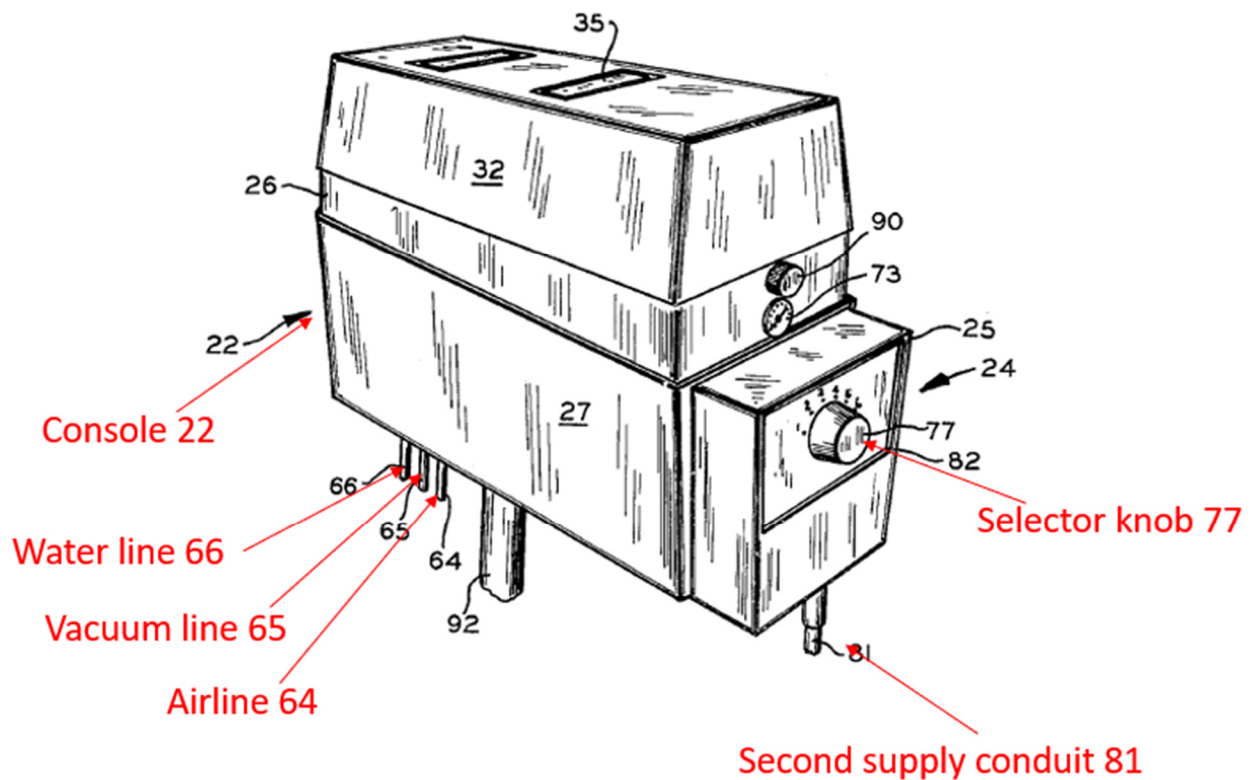
88. As shown in FIG. 1, Palmer's system comprises a handpiece means 14 in fluid communication with a plurality of solution reservoirs 12 (six shown) and a selector means 16 for selecting the fluid container. EUNSUNG-1005, Abstract, 4:50-68, FIG. 1. As discussed previously, FIG. 5A of Palmer's system comprises a selector valve means 20 which is a switchable manifold rotary valve

component. Having multiple input lumens, an output lumen, valving means, switching means, and a manifolding means, Palmer's selector valve means 20 predicts the manifold system, aka "block", of the '607 patent. As another example, Trueba discloses a fluid delivery system that includes multiple containers (e.g., Trueba's containers 50-56) and pump means (e.g., Trueba's ejection heads 40-46) that can selectively deliver the desired solution. EUNSUNG-1008, Abstract, 8:49-11:3, FIG. 3.



Trueba, FIG. 3 (annotated)

89. As another example, Armstrong discloses a medical fluid delivery system where the user can choose a desired fluid from several fluid containers (e.g., reservoirs 46). EUNSUNG-1011, Abstract, 2:12-15, 5:55-61, FIG. 1, FIG. 2, FIG. 7.

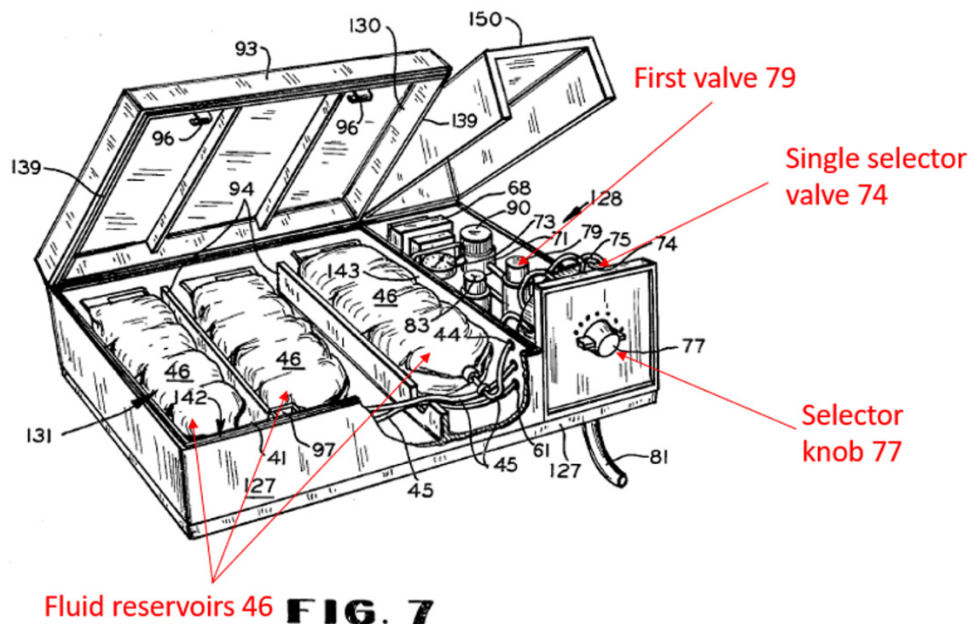


Armstrong, FIG. 2 (annotated)

90. Armstrong discloses in relevant part:

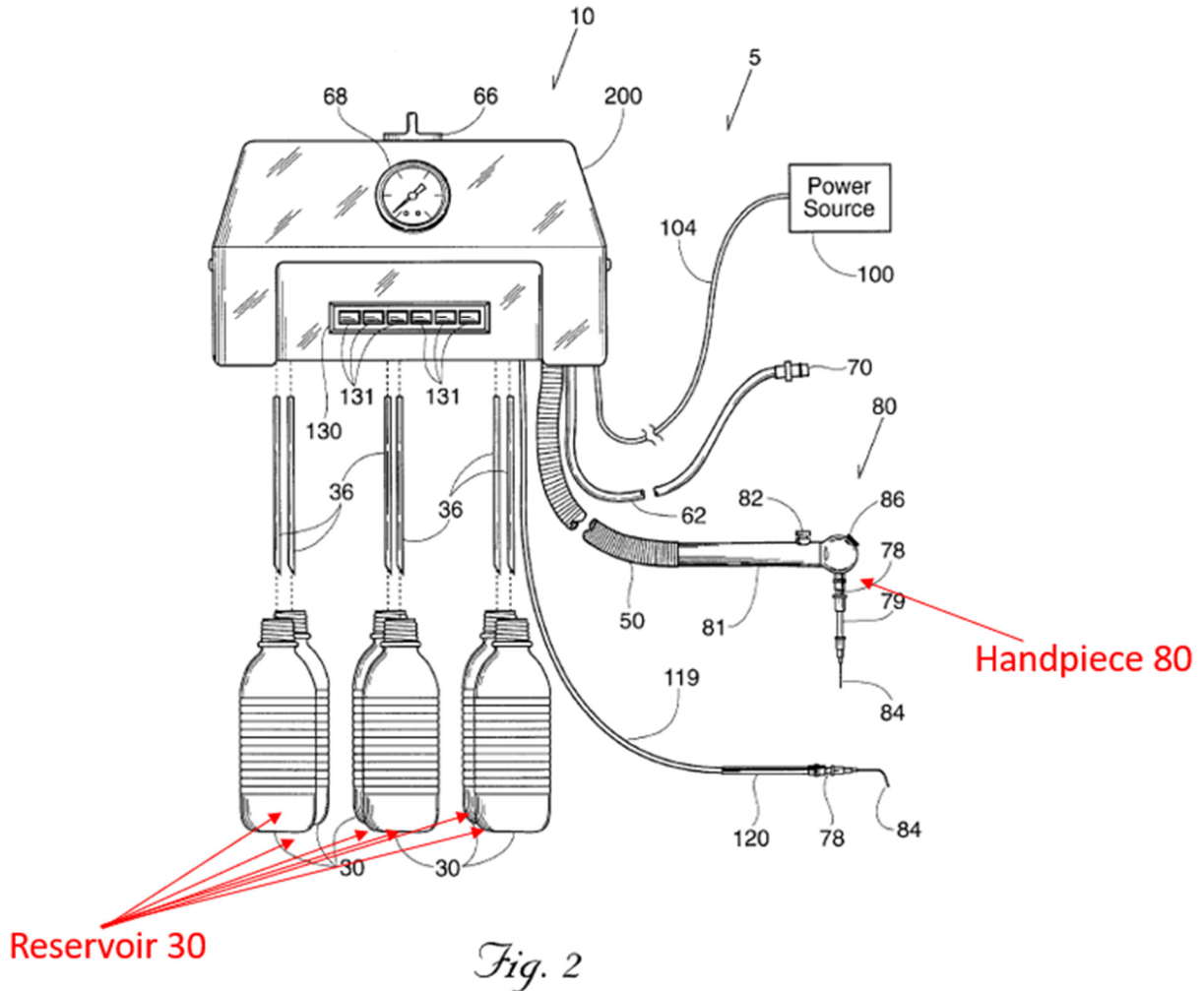
FIG. 2 shows the system 21 of FIG. 1 with the control box 82 secured to the supply station 22. In this embodiment the supply station 22 is supported by a pedestal 92 so that, if desired, the entire system 21 may be placed next to the patient treatment area. This embodiment is typically used in a dental care center as opposed to a surgical theater usage.

EUNSUNG-1011, 5:55-61. Armstrong depicts another console embodiment in FIG. 7 inclusive of fluid reservoirs, supply lines, actuation means, and a selector knob.



Armstrong, FIG. 7 (annotated)

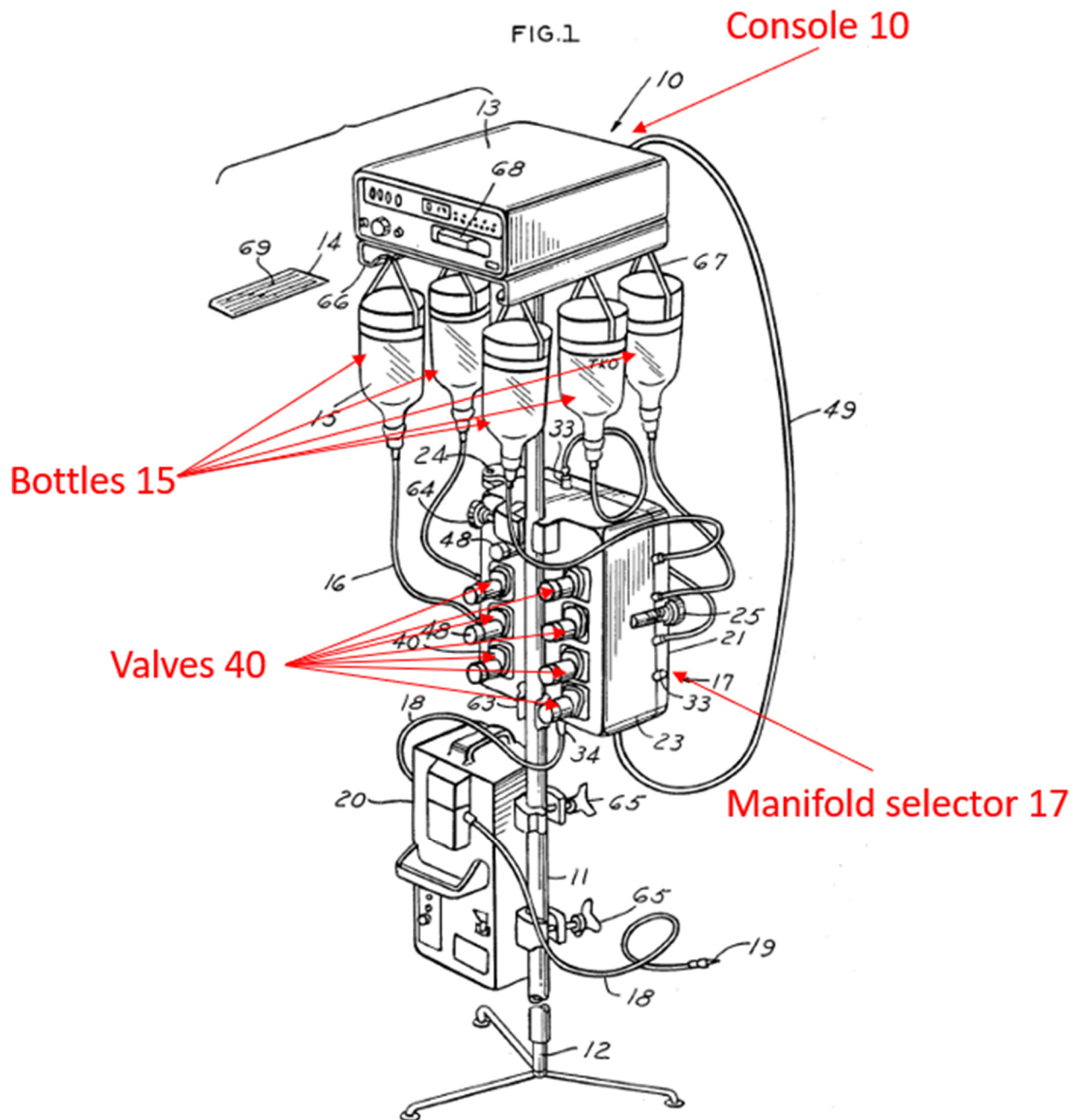
91. As another example, Pond discloses a fluid dispensing assembly that can be used to deliver the desired fluid from a plurality of fluid containers (e.g., reservoirs 30) to the handpiece (e.g., handpiece 80). EUNSUNG-1007, Abstract, 2:1-21, 4:41-67.



Pond, FIG. 2 (annotated)

92. As another example, Wunsch discloses an apparatus (e.g., console 10) for sequentially dispensing a plurality of solutions through a manifold (e.g., manifold selector 17) that is connected to each of the solutions to be administered. EUNSUNG-1020, Abstract, 7:39-56, 8:17-26, FIGS. 1-4. As shown in FIG. 1, the manifold selector 17 includes a plurality of valves 40, which control the flow of solution from the plurality of bottles 15. EUNSUNG-1020, 6:18-48, 7:16-56.

Attorney Docket No. 58484-0006IP1
IPR of U.S. Patent No. 12,052,607



Wunsch, FIG. 1 (annotated)

93. With this motivation and knowledge, a POSITA would have investigated other references such as Palmer to achieve benefits offered by multiple treatment solutions. As a first example, a POSITA would have been

motivated to modify Karasiuk based on Palmer's multiple containers and selector means to allow easy selection among multiple treatment solutions. EUNSUNG-1005, 1:30-53, 2:48-4:2. Palmer recognizes that "[c]onventional irrigation arrangements...generally do not provide the opportunity of easy selection among several irrigant solutions." EUNSUNG-1005, 1:30-53. "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," which "is time-consuming and costly, not to mention messy." *Id.* As a solution, Palmer proposed using multiple containers and selector means to allow selection among the different treatment solutions. EUNSUNG-1005, Abstract, 2:48-4:2, claim 1, FIG. 1.

94. As a second example, the combination would enable sequential delivery of different treatment solutions. EUNSUNG-1005, 6:46-51, 11:9-12. In this regard, Palmer discloses "[w]hen treatment with the particular irrigating solution is completed, **the system can be either switched to another solution**, or the selector knob may be turned to select the flush solution." EUNSUNG-1005, 11:9-12. Palmer also discloses "**a patient may be treated with two or more solutions during the same procedure, one after the other.**" EUNSUNG-1005, 6:46-51.

95. As a third example, the combination would minimize 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. EUNSUNG-1011, 2:7-10. A POSITA would have been motivated to achieve each of these benefits in Karasiuk and, thus, would have found it obvious to modify Karasiuk's microdermabrasion system based on Palmer's use of multiple containers with different treatment solutions and a selector to select among the treatment solutions.

96. In addition, a POSITA would have been motivated to adopt Palmer's modular design to provide the resulting system with added flexibility, organization and portability. EUNSUNG-1005, 9:58-10:2. In this regard, Palmer discloses "[b]y providing the reservoir storage means 32 in the form of modular single-shelf racks, a high degree of flexibility is provided" and the reservoir storage means can be placed on a countertop 168 (FIG. 11A), or on a mobile cart 170 (FIG. 11B) or in a cabinet 172 underneath a counter (FIG. 11C)." EUNSUNG-1005, 9:58-10:2. A POSITA would have viewed these modular/mobile benefits of Palmer as applicable to microdermabrasion systems, like Karasiuk's, and would have been motivated to use Palmer's console design in the microdermabrasion system resulting from the combination.

97. A POSITA would have had a reasonable expectation of success in such a combination. For example, both Karasiuk and Palmer are directed to

medical devices that deliver treatment solutions to treatment sites via a handpiece. EUNSUNG-1004, Abstract, [0013]-[0015], FIG. 6; EUNSUNG-1005, Abstract, 1:10-15, FIG. 1; EUNSUNG-1006, [0003]; EUNSUNG-1001, 6:53-56. Although Palmer describes an example related to dental work, Palmer's disclosure "relates generally to methods and apparatus for delivering liquid solutions to treatment sites." EUNSUNG-1005, 1:10-11. From this disclosure, a POSITA would have understood and found it obvious that Palmer's teachings are applicable to delivering fluids for other medical procedures (e.g., microdermabrasion). By the Critical Date, fluid delivery systems and techniques were largely standardized and were used commonly across various applications without undue experimentation. For example, as evidenced in Armstrong (cited by Palmer), "[w]hile the instrument is well adapted to dental work... it also supplies a need for a general purpose medical instrument." EUNSUNG-1011, Abstract.

98. In my opinion, replacement of Karasiuk's reservoir 70 with Palmer's multiple containers and selector means reflects a simple substitution of a known element for another to obtain predictable results—allowing selection of different treatment solutions. This replacement would also reflect the use of a known technique to improve similar devices in the same way. Indeed, a working microdermabrasion system was well-known to a POSITA, which allows selection of different treatment materials by including multiple containers and a selector

valve, as evidenced in Greenberg. EUNSUNG-1006, Abstract (“A valve [(30)] controls which supply container [(18, 26)] provides the treatment particles”), FIGS. 1 and 5.

2. Claim 1

[1.pre] A skin treatment system, comprising:

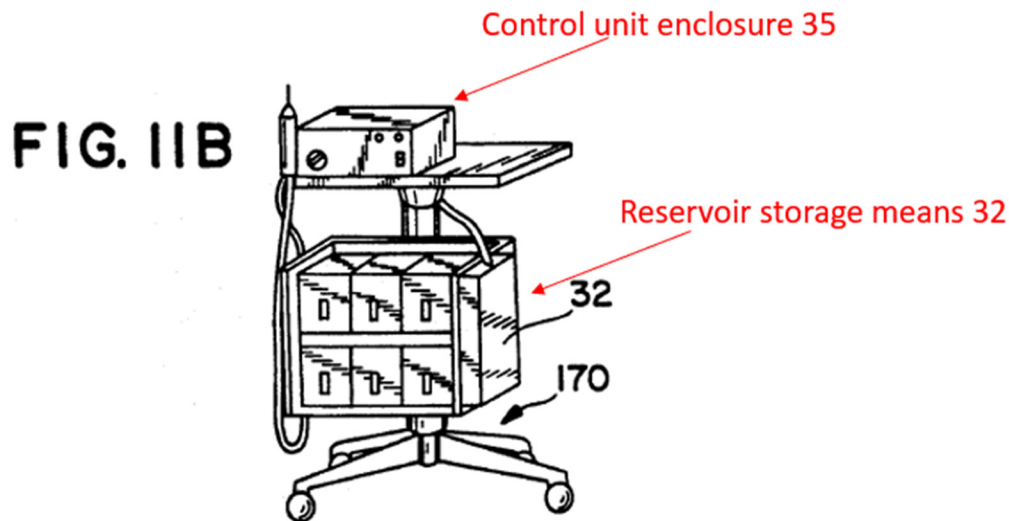
99. It is my opinion that Karasiuk-Palmer renders obvious a system (e.g., Karasiuk’s microdermabrasion system 30) for treating skin. Karasiuk, titled “Skin Treatment System and Method of Use,” discloses “a microdermabrasion device, microdermabrasion system employing the device, and method of performing microdermabrasion.” EUNSUNG-1004, [0014], Abstract, FIG. 6.

[1.1] a console configured to receive a first container containing a first treatment material and a second container containing a second treatment material;

100. It is my opinion that Karasiuk-Palmer renders obvious a console (e.g., Palmer’s mobile cart 170) configured to receive a first container (e.g., Palmer’s reservoir 12₁) containing a first treatment material (e.g., Palmer’s solution 34₁) and a second container (e.g., Palmer’s reservoir 12₂) containing a second treatment material (e.g., Palmer’s solution 34₂).

101. As discussed above in § XI.1, a POSITA would have been motivated to place Karasiuk’s handpiece, waste container, filter, and vacuum source in Palmer’s mobile cart 170 for increased portability and/or organization. In this regard, Palmer discloses providing the reservoir storage means in the form of a

console for increased portability and/or organization. EUNSUNG-1005, 9:58-10:2, FIGS. 11A-11C. Specifically, Palmer discloses: “[b]y providing the reservoir storage means 32 in the form of modular single-shelf racks, a high degree of flexibility is provided...the reservoir storage means 32 can be placed on a countertop 168 (FIG. 11A), or on a mobile cart 170 (FIG. 11B) or in a cabinet 172 underneath a counter (FIG. 11C).” EUNSUNG-1005, 9:63-10:2, FIGS. 11A-11C. For example, as shown in FIG. 11B, Palmer’s “mobile cart” includes modular blocks including a control unit enclosure 35 and a reservoir storage means 32. EUNSUNG-1005, FIG. 11B.



Palmer, FIG. 11B (annotated)

102. A POSITA would have understood that Palmer’s various structures, such as “countertop 168 (FIG. 11A),” “mobile cart 170 (FIG. 11B),” and “cabinet 172 underneath a counter (FIG. 11C),” constitute the claimed “console.” For

example, a POSITA would have understood that, in the combined device, both (1) Palmer's multiple containers and selector means and (2) Karasiuk's handpiece, waste container, filter, and vacuum source are placed in Palmer's mobile cart 170 (located on four casters) to provide added portability and/or organization, as taught by Palmer. EUNSUNG-1005, FIG. 11B.

103. This aligns with the disclosure of the '607 patent. For example, the '607 patent discloses that console 12 contains multiple containers (EUNSUNG-1001, 14:38-48), a valve system (EUNSUNG-1001, 9:18-20, 18:38-42), a handpiece (EUNSUNG-1001, 18:46-55), a vacuum pump (EUNSUNG-1001, 11:5-6, 18:38-45), a filter 28 (EUNSUNG-1001, 6: 6-8), a waste container (EUNSUNG-1001, 7:47-48), and is placed on four casters 33 for "easy movement" (EUNSUNG-1001, 6:13-14, FIG. 1).

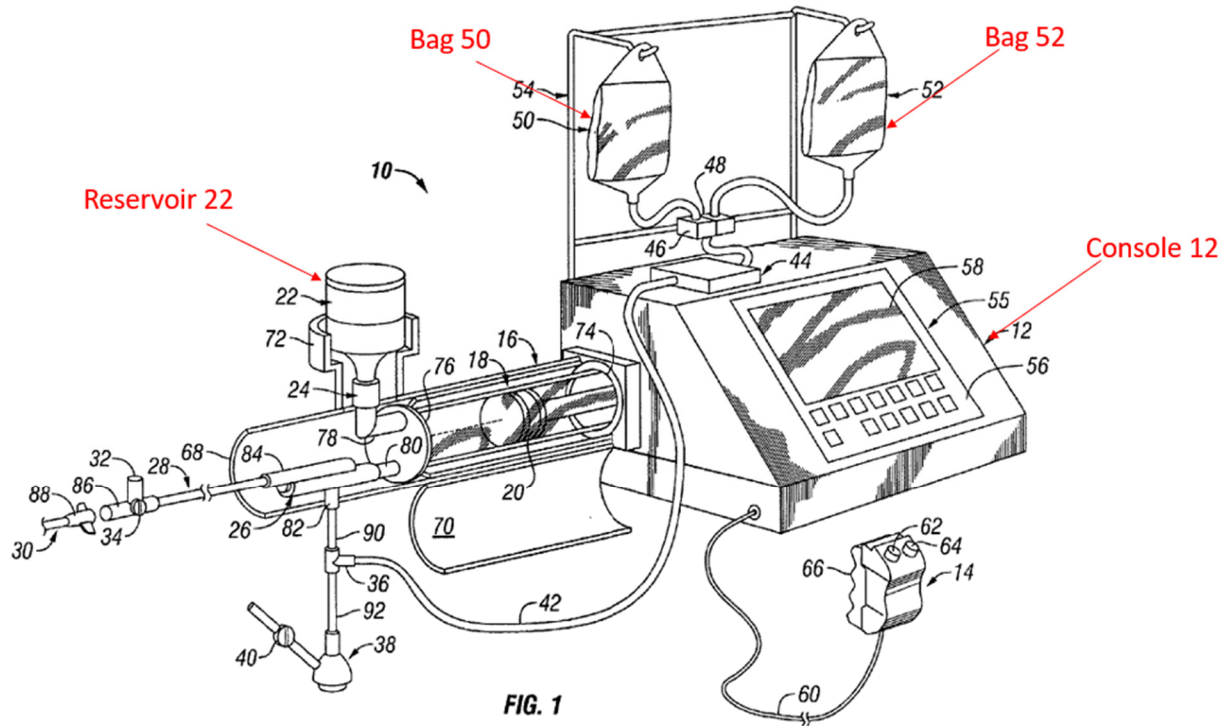
104. Alternatively or additionally, a POSITA would have been motivated and found it obvious to place Karasiuk-Palmer (including Palmer's multiple containers) in a console for increased portability and/or organization. Indeed, using a console to house similar medical devices were well-known and would have been within a POSITA's general knowledge. EUNSUNG-1010, FIGS. 2A-2G, 7A-7D, [0063] ("Console 12 houses the electrical controls for system 10, together with the motors which drive piston 20 and peristaltic pump 44."), [0088], [0154] ("The console and power supply are mounted to a cart, generally indicated at 402 which

includes wheels for easy movement and which is preferably designed to provide stability and deter tipping when used in its intended method”); EUNSUNG-1005, 9:58-10:2, FIGS. 11A-11C; EUNSUNG-1011, FIG. 2, 4:57-68, 5:55-61; EUNSUNG-1020, Abstract, 6:18-48, 7:16-56, 8:17-26, FIGS. 1-4. Indeed, a POSITA would have viewed a console as one of a finite number of options to achieve increased portability and/or organization that would have been obvious to try. A POSITA would have had a reasonable expectation of success to place the relevant components in a console, as it would constitute the use of a known technique to improve similar devices in the same way.

105. For example, Duchon discloses a medical fluid delivery system where the user can choose the desired fluid (e.g., contrast material or saline) from multiple fluid containers (e.g., reservoir 22 or bag 50). EUNSUNG-1010, Abstract, FIG. 1, [0006]. Duchon discloses in relevant part:

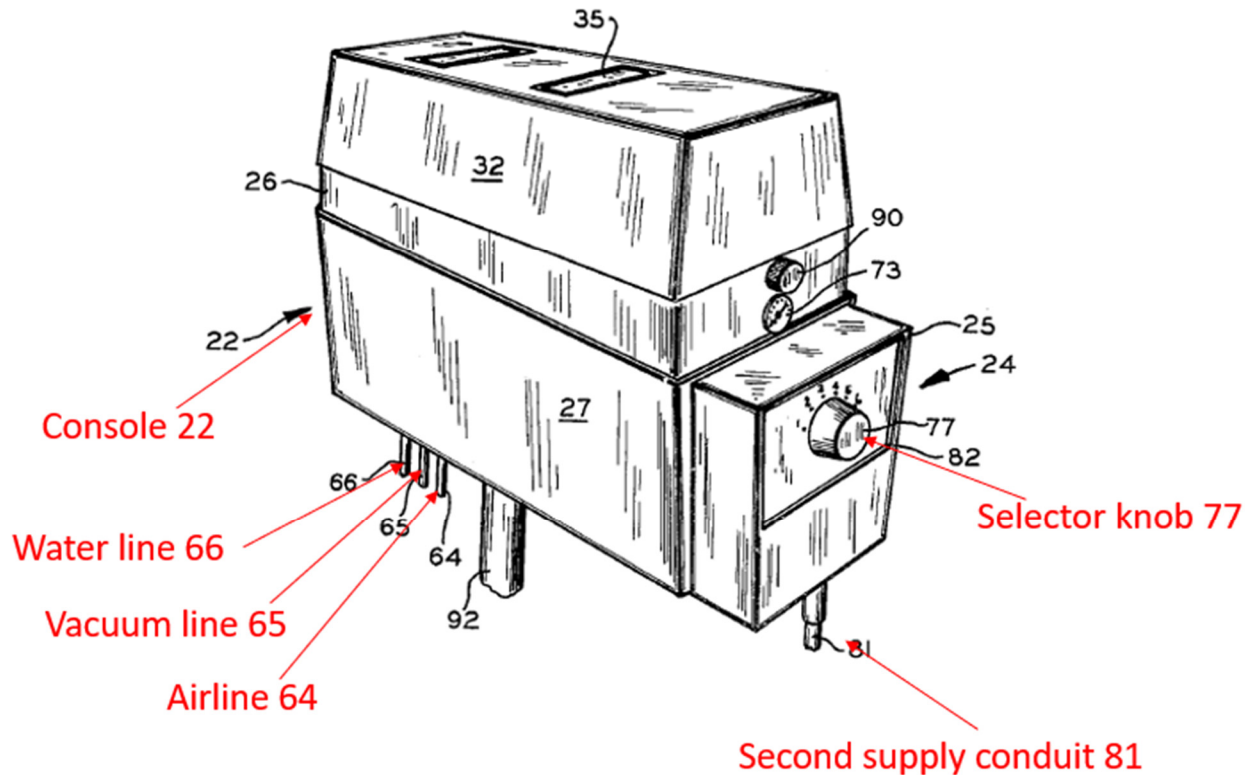
[0063] **Console 12** houses the electrical controls for system 10, together with the motors which drive piston 20 and peristaltic pump 44. On the front surface of **console 12**, user interface 55 provides control switches 56 and display 58 through which the user may enter control settings and monitor the operational state of system 10. The console can be free-standing, preferably configured for mounting on a transport cart assembly.

EUNSUNG-1010, [0063].



Duchon, FIG. 1 (annotated)

106. As another example, Armstrong discloses a medical fluid delivery system where the user can choose a desired fluid from several fluid containers (e.g., reservoirs 46). EUNSUNG-1011, Abstract, 2:12-15, 5:55-61, FIG. 1, FIG. 2, FIG. 7.



Armstrong, FIG. 2 (annotated)

107. Armstrong discloses in relevant part:

FIG. 2 shows the system 21 of FIG. 1 with the control box 82 secured to the supply station 22. In this embodiment the supply station 22 is supported by a pedestal 92 so that, if desired, the entire system 21 may be placed next to the patient treatment area. This embodiment is typically used in a dental care center as opposed to a surgical theater usage.

EUNSUNG-1011, 5:55-61.

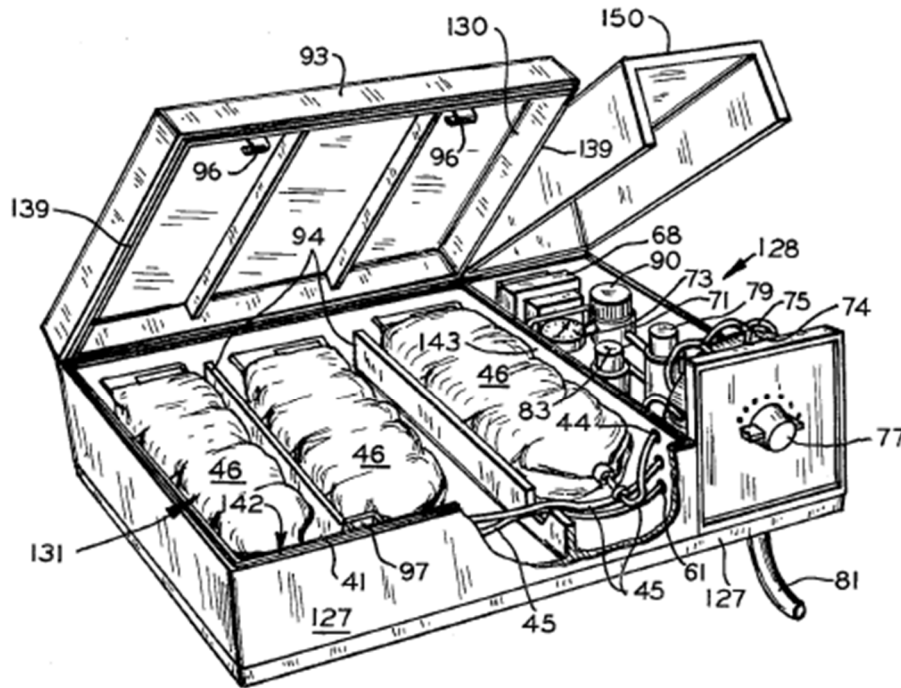
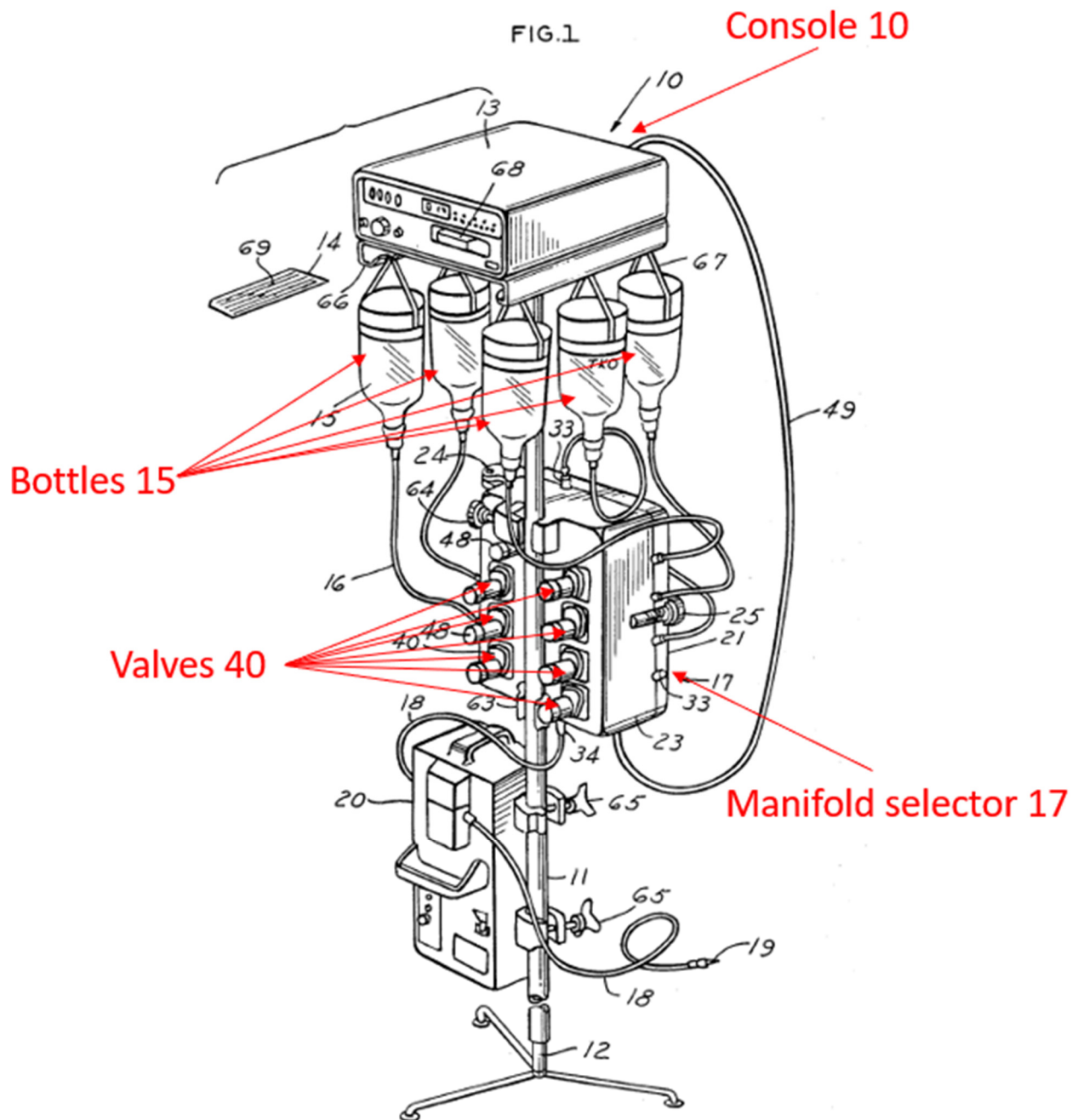


FIG. 7

EUNSUNG-1011, FIG. 7

108. As another example, Wunsch discloses an apparatus (e.g., console 10) for sequentially dispensing a plurality of solutions through a manifold that is connected to each of the solutions to be administered. EUNSUNG-1020, Abstract, 7:39-56, 8:17-26, FIGS. 1-4. As shown in FIG. 1, the manifold selector 17 includes a plurality of valves 40, which control the flow of solution from the plurality of bottles 15. EUNSUNG-1020, 6:18-48, 7:16-56. In operation, the user can program the sequencer timer 13 to automatically operate the valves 40 to achieve automatic switching between different solutions and sequential delivery of different solutions. EUNSUNG-1020, 9:36-10:64.



Wunsch, FIG. 1 (annotated)

109. Further, as I discussed in §XI.1, Karasiuk-Palmer describes six solution reservoirs in the modular structure (i.e., console), two of which would have been understood as first and second containers received at the console, and

for the reasons I explain below, it would have been obvious to a POSITA to use Palmer's multiple containers to hold different treatment materials.

110. Palmer's reservoirs each include "a quantity of a respective liquid solution substantially sealed within a container." EUNSUNG-1005, 4:53-57. Palmer also discloses using color-coding to distinguish a first treatment solution in a first container from a second treatment solution in a second container. EUNSUNG-1005, 5:37-6:32 (explaining that the six containers may contain, respectively, an aqueous bacteriostatic rinse solution, a 1% zinc chloride solution, a 2% sodium fluoride solution, a 1.64% stannous fluoride gel, a 0.12% chlorhexidine gluconate, and a 1.7% hydrogen peroxide solution).

111. Karasiuk also recognizes the desirability of using multiple types of skin treatment solutions during microdermabrasion. EUNSUNG-1004, [0024], [0047] ("application of lotions/vitamins or other fluids"), [0061] (listing various treatment solutions). Specifically, Karasiuk discloses:

Reservoir 70 may contain solution or a suspension for purposes other than abrasion or pure abrasiveness. General examples, types and/or categories of compounds that may be employed include: beaching formulations (e.g., 2-4% hydroquinone, 2% Kojic Acid, 1% Vitamin K, and 1% Hydrocortisone in a aqueous base); acne treatment formulations (e.g., Salycilic Acid, alcohol base buffered by witch hazel, etc.); fine lines/wrinkle treatment formulations (e.g., Hyaluronic acid in an aqueous base); hydrating formulations (e.g., Calendula, vitamins A, D and/or E in a mineral oil base); antioxidant formulations/free radical scavengers (e.g., vitamins A, E and K in a mineral oil base). Other examples of product categories that may be employed

alone or in combination with other compounds include, antiseptics, astringents, cleansers, pore decongestants, balms, botanicals, collagen stimulators, herbs, microemulsifiers, oxygen delivery vehicles, proteins, serums, skin firming agents, toners, topical anesthetics, and tyrosinase inhibitors. Individually named products as may be used (with associated benefit indicated parenthetically) include: Aloe Vera (calming); alpha hydroxy acids (peel); alphasalicylic acid (antioxidant); benzoyl and other peroxides (acne); ceramide (hydrator); copper (toning); copper peptide (toning); CoQ-10 (coenzyme Q-10) and other enzymes (toning); cortisone (calming); glycolic acids (peel); hyaluronic acid (collagen stimulation); hydrolipids (hydrator); hydroquinones (bleaching); lactic acids (peel); magnesium ascorbic phosphate (free radical scavenger, collagen stimulator, bleaching); niacin (vascular dilation); phospholipids (moisturization); potassium (toning, psoriasis), and salicylic acids (acne). Of course, any combination of such elements may be provided--even in connection with abrasive particles.

EUNSUNG-1004, [0061].

112. Karasiuk further discloses the use of abrasive member 24 which predicts the use of an abrasive inner member or abrasive pad comprised within the handpiece. EUNSUNG-1005, [0048], [0055], [0066]-[0069]. Indeed, surface-based (as opposed to free particle-based) dermabrasion was known by the Critical Date of the '607 patent. EUNSUNG-1027 (Waldron-739), Figs. 4-14. Furthermore, Waldron-739 indicates "delivery of a supplemental fluid" to the handpiece, such fluid described inclusively as "... liquids to reduce friction." EUNSUNG-1027, 3:3-4, 6:5-6. Thus, both Karasiuk and Waldron-739 predict the use of surface-based dermabrasion with delivery of treatment fluids to the treatment area.

113. In the Karasiuk-Palmer combination, it would have been obvious to

use Palmer's multiple containers (e.g., Palmer's reservoirs 12₁-12₆) to hold different treatment fluids as taught by Karasiuk and Palmer—for example, a first container may hold an antioxidant formulation (e.g., vitamin) for skin treatment and a second container may hold a hydrating formulation (e.g., lotion) for skin treatment. EUNSUNG-1004, [0061]; EUNSUNG-1005, 5:37-6:32 (explaining that the six containers may contain, respectively, an aqueous bacteriostatic rinse solution, a 1% zinc chloride solution, a 2% sodium fluoride solution, a 1.64% stannous fluoride gel, a 0.12% chlorhexidine gluconate, and a 1.7% hydrogen peroxide solution); EUNSUNG-1013, 86 (“The skin can then be rinsed with tepid water and a moisturizer with adequate sunscreen applied”); EUNSUNG-1016, Abstract (“The flux and skin deposition of vitamin C across microdermabrasion-treated skin was approximately 20-fold higher than that across intact skin.”).

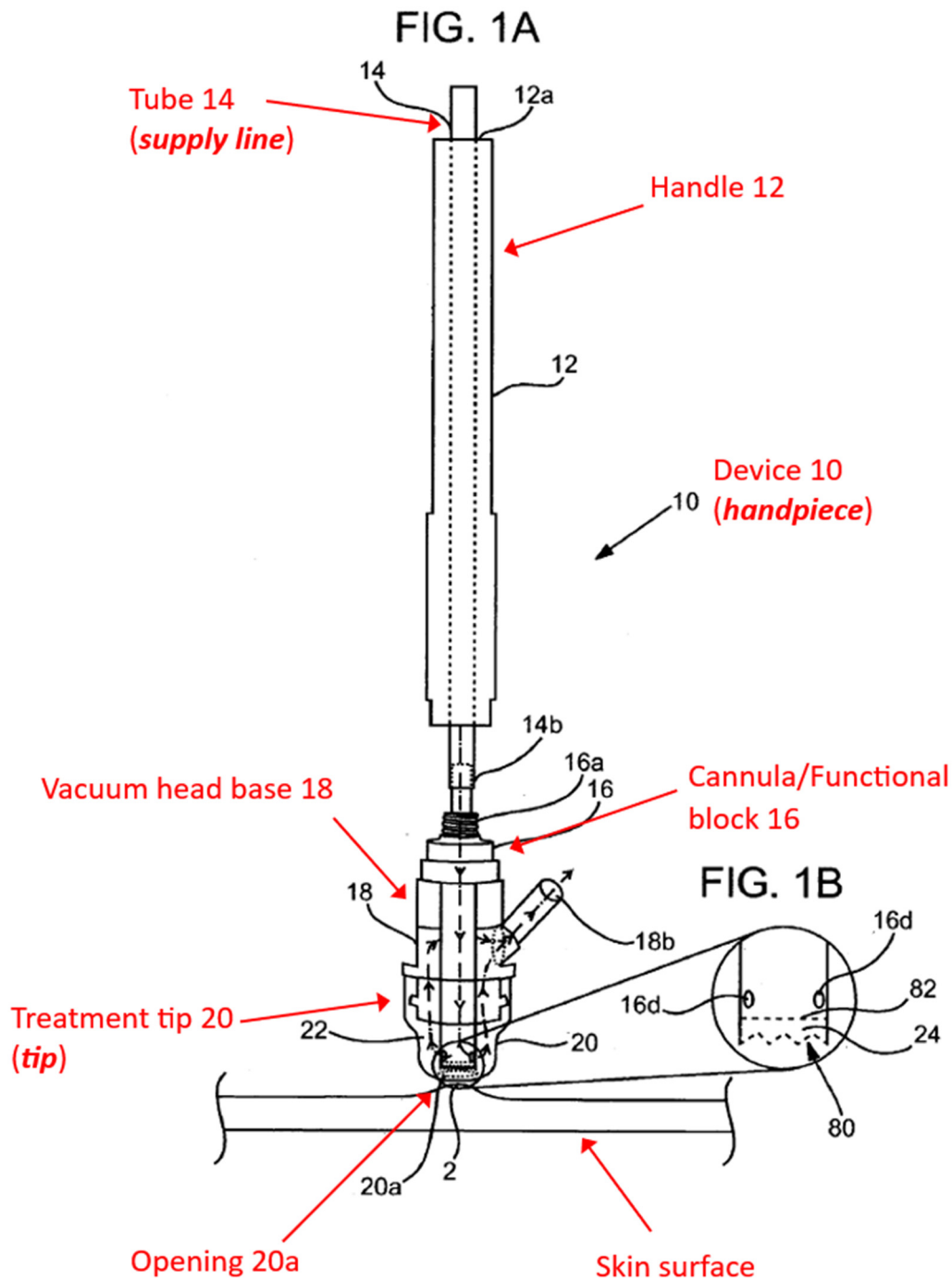
114. Thus, Karasiuk-Palmer renders obvious a console (e.g., Palmer's mobile cart 170) configured to receive a first container (e.g., Palmer's reservoir 12₁) containing a first treatment material (e.g., Palmer's solution 34₁) and a second container (e.g., Palmer's reservoir 12₂) containing a second treatment material (e.g., Palmer's solution 34₂).

[1.2] a handpiece configured to couple to a tip that can be pressed against skin to perform skin treatment;

115. It is my opinion that the Karasiuk-Palmer combination renders obvious a handpiece (e.g., Karasiuk's device 10) configured to couple to a tip (e.g.,

Karasiuk's treatment tip 20) that can be pressed against skin to perform skin treatment.

116. For example, Karasiuk states that “[d]evice 10 is designed to be **handheld by a user** for its application to the skin of a patient in the performance of microdermabrasion or other vacuum therapy application.” EUNSUNG-1004, [0044] (“an elongated handle 12 to facilitate grasping by a user”), [0045] (“Cannula 16 runs through the center of the handpiece”). Karasiuk's device 10 is depicted in FIG. 1A, reproduced below.



Karasiuk, FIG. 1 (annotated)

117. Karasiuk's device 10 includes a handle 12, which receives tube 14 on one end and connects to functional block 16 (also referred to as "cannula 16") on

the other. EUNSUNG-1004, [0044]-[0046], FIG. 1A. A “vacuum head base 18 is fitted over functional block 16” and “[a] treatment tip 20 is fitted over the end of vacuum base 18.” *Id.*, [0046]-[0048], FIG. 1A. Karasiuk explains that treatment tip 20 is coupled to device 10’s vacuum head base 18 through a “friction fit and/or provided with threads or other attachment means to provide a pressure tight fit between the components.” *Id.*, [0047].

118. Karasiuk’s treatment tip 20 “includes an opening 20a which targets an area of skin to be contacted (e.g., to be microabraded) when tip 20 is applied to the skin.” *Id.*, [0047], FIG. 1A. Karasiuk describes treatment tip 20 as “smooth surfaced and adapted to glide over the skin surface” and further states that “device 10 is positioned so as to place tip 20 *in contact with the skin surface* to be microabraded.” EUNSUNG-1004, [0047], [0063]-[0064], [0069], FIG. 1A.

119. Karasiuk describes an alternative embodiment in which treatment “tip 20 may be integrally machined or molded with vacuum head base 18,” which in turn mates with functional block/cannula 16. EUNSUNG-1004, [0048]. Karasiuk further provides that cannula 16 may be constructed such that abrasive/non-abrasive member 24 “could be mounted to the inner walls of a vacuum head base with several spokes, . . . with the remainder of the cannula then simply being replaced by an extension of tube 14.” *Id.*, [0068]. In these alternative embodiments, a POSITA would have recognized Karasiuk’s treatment tip 20, vacuum head base

18, and cannula 16 as corresponding to the claimed “tip that can be pressed against skin to perform skin treatment.” *See id.*, [0042] (“The term ‘tip’ refers to the end of a structure or assembly. As used herein, the applicator tip is that component, whether integral or attachably fixed to the device, which is the endmost extremity of the device and is used in contacting the skin.”). As depicted in Karasiuk’s FIG. 1, the tip formed by treatment tip 20, vacuum head base 18, and cannula 16 is configured to couple to handle 12 of device 10 through, for example, threading. EUNSUNG-1004, [0045], FIGS. 1-2.

120. Thus, a POSITA would have understood Karasiuk as teaching the claimed handpiece (e.g., device 10) configured to couple (e.g., through a friction fit or threads) to a tip (e.g., treatment tip 20) that can be pressed against skin to perform skin treatment (e.g., microdermabrasion).

[1.3] a supply line connected between the handpiece and the console for sequentially delivering treatment material to the handpiece from the first container or the second container;

121. It is my opinion that the Karasiuk-Palmer combination renders obvious a supply line (e.g., Karasiuk’s tube 14 and/or Palmer’s second tubing means 30) connected between the handpiece (e.g., device 10) and the console (e.g., Palmer’s mobile cart 170) for sequentially delivering treatment material (e.g., Palmer’s solutions 12₁-12₆) to the handpiece from the first container (e.g., Palmer’s solution reservoir 12₁) or the second container (e.g., Palmer’s solution reservoir

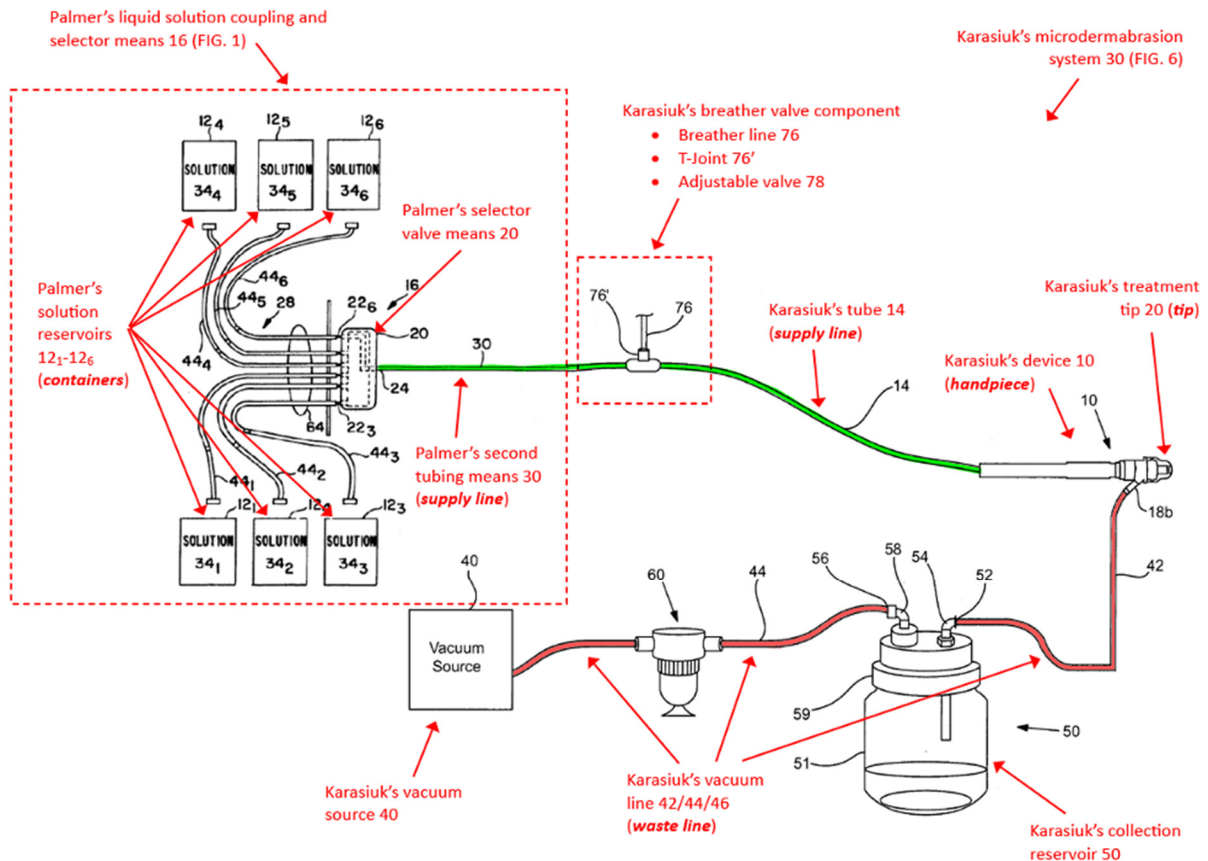
12₂).

122. For example, Karasiuk explains that its device 10 is connected to a fluid reservoir 70 through tube 14 (also referred to as “fluid delivery line 14”). EUNSUNG-1004, [0044]-[0045], [0059]. Fluid reservoir 70 contains treatment material (e.g., “[a]brasive particles, such as corundum crystals, sodium bicarbonate crystals or other abrasive particles”) for “delivery through the system to perform a microabrading function.” *Id.*, [0060]-[0061].

123. Similarly, Palmer’s system provides a second tubing means 30, which extends from Palmer’s handpiece means 14 to Palmer’s selector valve means 20. EUNSUNG-1005, 5:1-9, 10:60-62. Palmer’s selector valve means 20 provides for fluid communication between one of Palmer’s solution reservoirs 12₁-12₆ and Palmer’s handpiece means 14 by way of second tubing means 30. *Id.*; *see also supra* § X.2. Palmer’s selector valve means 20 is located in control unit enclosure 35, which Palmer explains may be located on Palmer’s mobile cart 170. EUNSUNG-1005, 5:10-18, FIGS. 4, 11B; *see also supra* § X.2.

124. As discussed in § XI.1, Karasiuk-Palmer replaces Karasiuk’s reservoir 70 with Palmer’s multiple reservoirs and “liquid solution coupling and selector means 16” to allow selection of different treatment solutions. In the resulting combination, it would have been obvious to a POSITA to connect Karasiuk’s device 10 to Palmer’s selector valve means 20 through a supply line comprising

Karasiuk's tube 14 and Palmer's second tubing means 30. EUNSUNG-1004, [0054], FIG. 1; EUNSUNG-1005, 5:16-18; *see supra* § XI.1. The supply line in the Karasiuk-Palmer combination is depicted below in green.

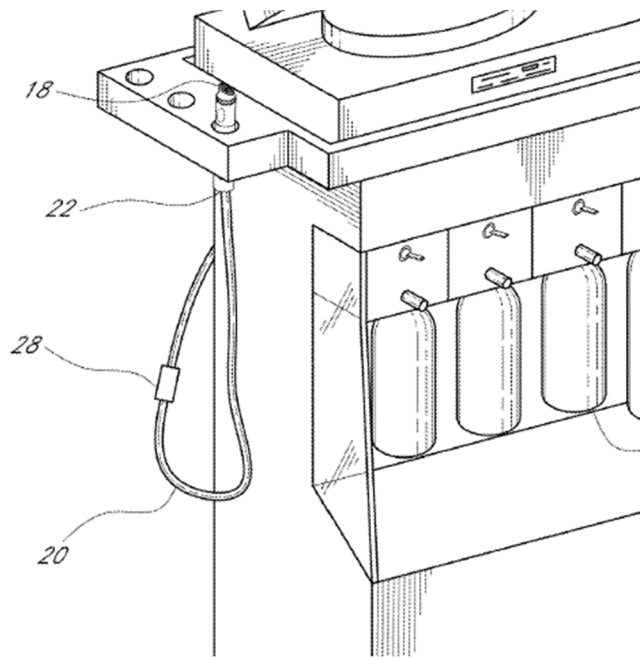


Karasiuk, Modified FIG. 6

125. Because Palmer's selector valve means 20 is located in control unit enclosure 35 on Palmer's mobile cart 170, a POSITA would have understood that the supply line in the Karasiuk-Palmer combination is "connected between" Karasiuk's device 10 and Palmer's mobile cart 170.

126. This aligns with the disclosure of the '607 patent. The '607 patent

states that line 20, which includes the supply line/input line 52 and waste line/output line 50, “is configured to provide fluid communication between the containers 26 and the handpiece assembly 18.” EUNSUNG-1001, 5:64-66; *see also id.*, 19:29-59. “The line 20 can comprise one or more conduits extending between the console 12 and the handpiece assembly 18.” *Id.*, 5:66-6:1. The ’607 patent does not describe nor depict either line connecting to an intermediate component, such as a port or receiver, on the console. *See id.*, 5:64-6:13, 19:29-59, FIGS. 1, 16.



’607 Patent, FIG. 1 (excerpt)

127. I have been asked to consider whether it would have been obvious to a POSITA to connect the supply line of the Karasiuk-Palmer system to an intermediate component located within or upon mobile cart 170, such as a port or

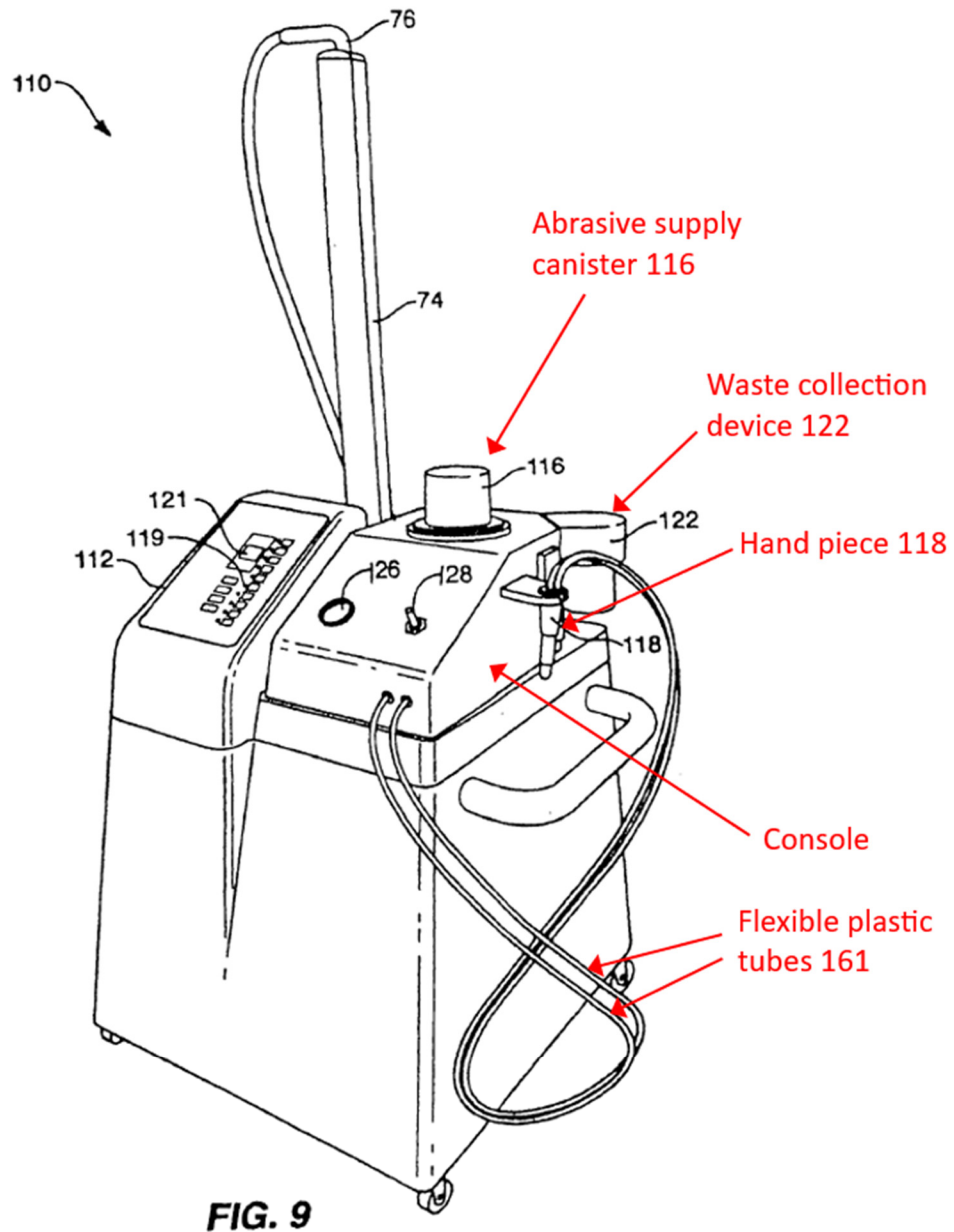
receiver, before then connecting to other components located within or upon mobile cart 170. I believe it would.

128. In my opinion, choosing to connect supply and waste lines (e.g., Karasiuk's tube 14 and vacuum line 42/44/46) to an intermediate component, such as a port or receiver on the console (e.g., Palmer's mobile cart 170), before ultimately connecting to other components located within or upon the console (e.g., Palmer's selector valve means 20 or Karasiuk's collection reservoir 50) would have been an obvious design choice. Choosing to do so would not result in any functional differences, would be well within the knowledge and skill of a POSITA, would yield expected results. Additionally, choosing to connect the supply and waste lines to a component such as a port or receiver on the console before connecting to other components located in or upon the console merely reflects the use of a known technique of arranging supply and waste lines in a microdermabrasion system to improve similar devices in the same way.

129. In fact, it was known in the art and within the general knowledge of a POSITA to connect supply and waste lines between a handpiece and an intermediate component, such as a port or receiver on a console before the critical date of the '607 patent. For example, Ramey discloses a microdermabrasion system with a console and a handpiece, which are in fluid communication through a pair of flexible tubes extending/connecting between a console and a handpiece.

EUNSUNG-1028, 12:62-14:35, 17:12-33, FIG. 9. Ramey's system is depicted

below in FIG. 9.



Ramey, FIG. 9 (annotated)

130. Specifically, Ramey discloses a portable dermabrasion apparatus 110,

which includes a vacuum generator 112, abrasive supply canister 116, waste collection device 122, and hand piece 118. EUNSUNG-1028, 12:62-14:35, FIG. 9. While not specifically labeled, a POSITA would have recognized that the enclosure containing the abrasive supply cannister 116, waste collection device 122, and various controls for the dermabrasion device may be considered a console. *See supra* limitation 1.1.

131. Ramey's hand piece 118 contains two apertures, supply aperture 165 and return aperture 167, which couple to feeding device 114 (which in turn couples to abrasive supply cannister 116) and waste collection device 122, respectively, via flexible plastic tubes 161. EUNSUNG-1028, 17:12-32, 13:24-26, FIGS. 9, 10, 12A. A POSITA would have readily appreciated that the flexible plastic tube connected between the supply aperture 165 and feeding device 114 may be considered a supply line and that the flexible plastic tube connected between return aperture 167 and waste collection device 122 may be considered a waste line. As depicted in FIG. 9, Ramey teaches receiving flexible plastic tubes 161 (i.e., supply and waste lines) on the front of Ramey's console before connecting to feeding device 114 or waste collection device 122 located within or upon Ramey's console. *Id.*, FIG. 9.

132. Thus, a POSITA would have understood the combination of Karasiuk and Palmer as teaching or rendering obvious a supply line (e.g., Karasiuk's tube

14) connected between the handpiece (e.g., device 10) and the console (e.g., Palmer's mobile cart 170).

133. In my opinion, the combined teachings of Karasiuk and Palmer also render obvious using the supply line for sequentially delivering treatment material (e.g., Palmer's solution 34₁ or 34₂) to the handpiece (e.g., Karasiuk's device 10) from the first container (e.g., Palmer's solution reservoir 12₁) or second container (e.g., Palmer's solution reservoir 12₂).

134. The Karasiuk-Palmer system includes "a selector valve for fluidly coupling the handpiece to a selected one of the liquid solutions" contained in "a plurality of solution reservoirs 12," as taught by Palmer. EUNSUNG-1005, Abstract, FIG. 1, FIGS. 5A-5C. In addition, Palmer describes a "liquid solution coupling and selector means, generally designated 16, for coupling handpiece means 14 to a selected one of the liquid solutions in a respective solution reservoir 12..." EUNSUNG-1005, 4:50-63. Specifically, Palmer's selector valve means 20 selects which one of reservoirs 12₁-12₆ is connected to the handpiece. EUNSUNG-1005, 8:6-21 ("selector valve means 20 comprises a main body 70 having a central cylinder core or stem 72 rotatably mounted therein."), FIG. 1. Palmer illustrates an exemplary selector valve means 20 in FIGS. 5A-5C.

135. Palmer further discloses that, "[w]hen treatment with the particular irrigating solution is completed, the system can be either switched to another

solution, or the selector knob may be turned to select the flush solution.” Palmer 11:9-12. Palmer also discloses that “a patient may be treated with two or more solutions during the same procedure, one after the other.” EUNSUNG-1005, 6:46-51. Karasiuk recognizes the desirability of using multiple types of skin treatment solutions during microdermabrasion. EUNSUNG-1004, [0024], [0047] (“application of lotions/vitamins or other fluids”), [0061] (listing various treatment solutions). In the Karasiuk-Palmer combination, it would have been obvious to use Palmer’s multiple containers to sequentially deliver different skin treatment solutions—for example, a first container may hold an antioxidant formulation (e.g., vitamin) and a second container may hold a hydrating formulation (e.g., lotion). EUNSUNG-1004, [0061]; EUNSUNG-1005, 5:37-6:32 (explaining that the six containers may contain, respectively, an aqueous bacteriostatic rinse solution, a 1% zinc chloride solution, a 2% sodium fluoride solution, a 1.64% stannous fluoride gel, a 0.12% chlorhexidine gluconate, and a 1.7% hydrogen peroxide solution); EUNSUNG-1013, 86 (“The skin can then be rinsed with tepid water and a moisturizer with adequate sunscreen applied”); EUNSUNG-1016, Abstract (“The flux and skin deposition of vitamin C across microdermabrasion-treated skin was approximately 20-fold higher than that across intact skin.”).

136. It is my opinion that a POSITA would have understood that the term “sequentially” only requires that a first treatment fluid and a second treatment fluid

be delivered one after another, as opposed to “simultaneously,” and does not require automatic switching between treatment fluids. However, to the extent that this term is interpreted to require automatic switching between treatment fluids, this feature is obvious in view of knowledge of the POSITA. For example, Trueba discloses “[c]omputerized control of medication dosing, which may be programmed by medical personnel for subsequent automated delivery, can help avoid toxic drug interactions, overdoses, and deaths.” EUNSUNG-1008, 6:6-9. As another example, Wunsch discloses that the user can program the sequencer timer 13 to automatically operate the valves 40 to achieve automatic switching between different solutions and sequential delivery of different solutions. EUNSUNG-1020, 9:36-10:64.

137. From this disclosure, the Karasiuk-Palmer combination renders obvious using the supply line for sequentially delivering treatment material (e.g., Palmer’s solution 34₁ or 34₂) to the handpiece (e.g., Karasiuk’s device 10) from the first container (e.g., Palmer’s solution reservoir 12₁) or second container (e.g., Palmer’s solution reservoir 12₂).

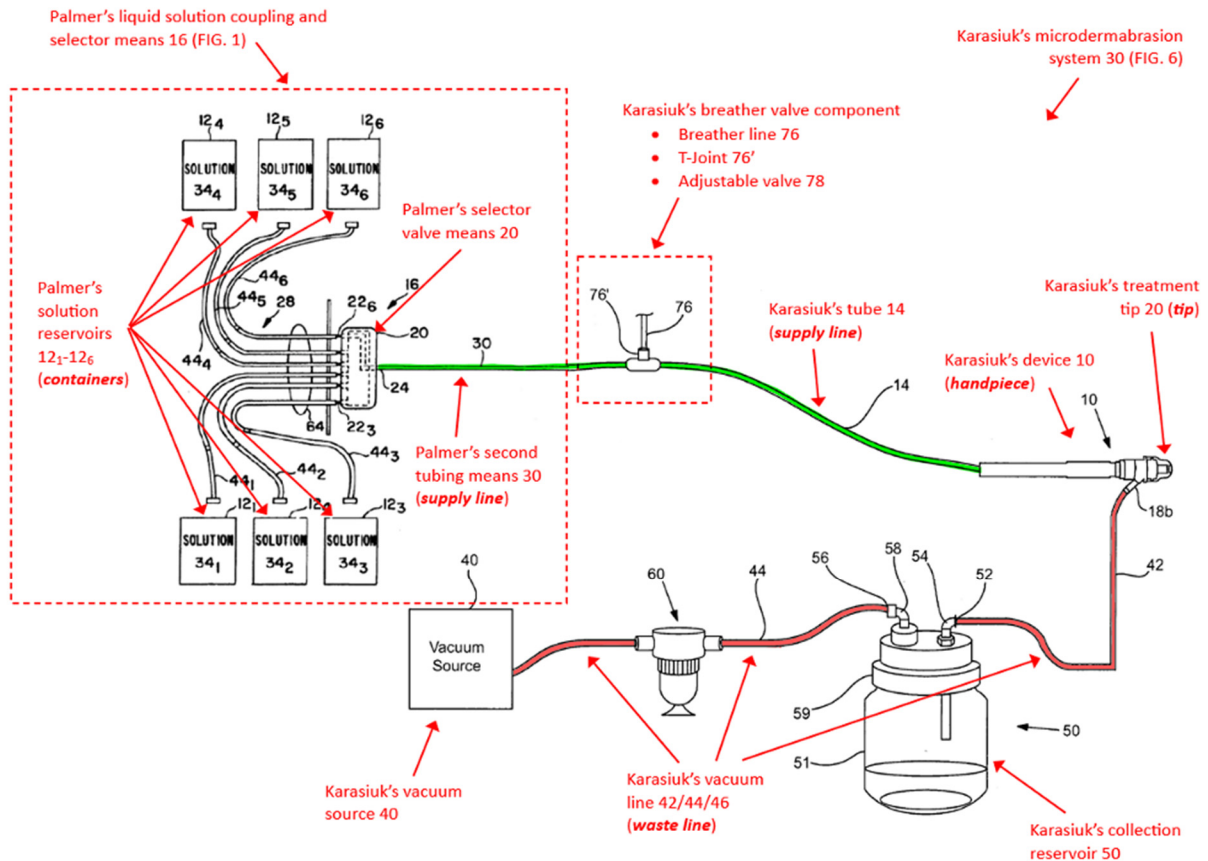
138. Thus, a POSITA would have understood the combined teachings of Karasiuk and Palmer as rendering obvious a supply line (e.g., Karasiuk’s tube 14 and/or Palmer’s second tubing means 30) connected between the handpiece (e.g., device 10) and the console (e.g., Palmer’s mobile cart 170) for sequentially

delivering treatment material (e.g., Palmer's solutions 12₁-12₆) to the handpiece from the first container (e.g., Palmer's solution reservoir 12₁) or the second container (e.g., Palmer's solution reservoir 12₂).

[1.4] a waste line connected between the handpiece and the console; and

139. It is my opinion that the Karasiuk-Palmer combination renders obvious a waste line (e.g., Karasiuk's vacuum line 42) connected between the handpiece (e.g., Karasiuk's device 10) and the console (e.g., Palmer's mobile cart 170).

140. For example, Karasiuk explains that device 10 is connected to collection reservoir 50 (i.e., a waste container) and vacuum source 40 through a vacuum line (e.g., collectively vacuum line 42, second vacuum line 44, vacuum line 46) (respectively or collectively ***waste line***). EUNSUNG-1004, [0056]-[0057], FIG. 6. The waste line in the Karasiuk-Palmer combination is depicted below in red.



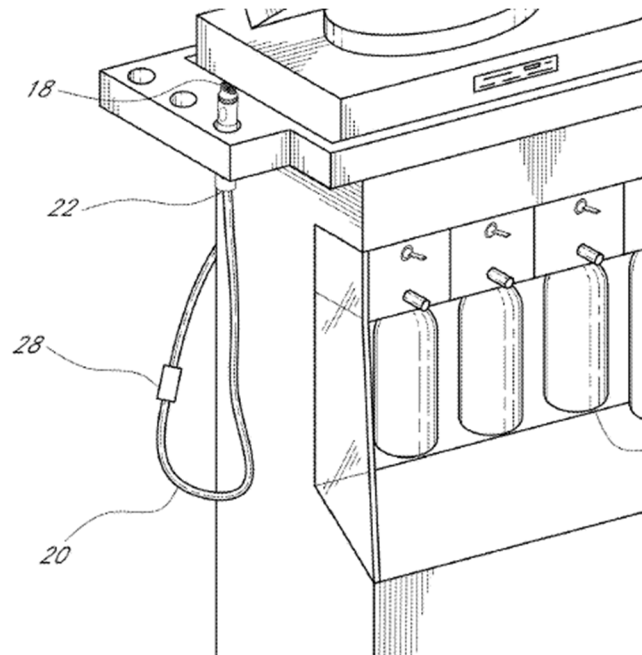
Karasiuk, Modified FIG. 6

141. Karasiuk explains that device 10 is connected with vacuum source 40 through vacuum line 42. EUNSUNG-1004, [0056]. Specifically, vacuum line 42 connects with device 10 at vacuum opening 18b on one end and connects to an input 52 to collection reservoir 50 on the other end. *Id.* An optional “back-up filter 60 may be provided . . . as added insurance that no or substantially no fluid, skin particles, abrasive particle or other materials being collected by the collection reservoir 50 can be transported to vacuum source 40.” *Id.*, [0057]. Back-up filter 60 may be connected to output 56 of collection reservoir 50 through second

vacuum line 44 and to vacuum source 40 through third vacuum line 46. *Id.*

142. A POSITA would have understood Karasiuk's vacuum line 42, vacuum line 44, and/or vacuum line 46 as teaching a waste line. As explained above with respect to limitation 1.1, in the Karasiuk-Palmer combination, a POSITA would have been motivated to place Karasiuk's collection reservoir 50 and vacuum source 40 in Palmer's mobile cart 170 to provide added flexibility, organization, portability, and protection. Because Karasiuk's collection reservoir 50 is located in Palmer's mobile cart 170, a POSITA would have understood that the waste line in the Karasiuk-Palmer combination is "connected between" Karasiuk's device 10 and Palmer's mobile cart 170.

143. This aligns with the disclosure of the '607 patent. The '607 patent states that line 20, which includes the supply line/input line 52 and waste line/output line 50, "is configured to provide fluid communication between the containers 26 and the handpiece assembly 18." EUNSUNG-1001, 5:64-66; *see also id.*, 19:29-59. "The line 20 can comprise one or more conduits extending between the console 12 and the handpiece assembly 18." *Id.*, 5:66-6:1. The '607 patent does not describe nor depict either line connecting to an intermediate component, such as a port or receiver, on the console. *See id.*, 5:64-6:13, 19:29-59, FIGS. 1, 16.



'607 Patent, FIG. 1 (excerpt)

144. I have been asked to consider whether it would have been obvious to a POSITA to connect the waste line of the Karasiuk-Palmer system to an intermediate component located within or upon mobile cart 170, such as a port or receiver on mobile cart 170, before then connecting to other components located within or upon mobile cart 170. I believe it would have been obvious to a POSITA to connect the waste line to an intermediate component located within or upon mobile cart 170 for similar reasons to those explained above with respect to the supply line in limitation 1.3.

145. Thus, a POSITA would have understood the combined teachings of Karasiuk and Palmer as rendering obvious a waste line (e.g., Karasiuk's vacuum line 42) connected between the handpiece (e.g., Karasiuk's device 10) and the

console (e.g., Palmer's mobile cart 170).

[1.5] a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is pressed against skin.

146. It is my opinion that the Karasiuk-Palmer combination renders obvious a vacuum source (e.g., Karasiuk's vacuum source 40) configured to create a vacuum that draws waste material from the handpiece (e.g., Karasiuk's device 10) through the waste line (e.g., Karasiuk's vacuum line 42) for disposal and that draws treatment material (e.g., Palmer's solutions 12₁-12₆) from either the first container (e.g., Palmer's reservoir 12₁) or the second container (e.g., Palmer's reservoir 12₂) to the handpiece (e.g., Karasiuk's device 10) when the tip (e.g., Karasiuk's treatment tip 20) is pressed against skin.

147. For example, Karasiuk describes a vacuum source 40 configured to create a vacuum used in performing microdermabrasion. EUNSUNG-1004, [0021], [0038], [0056]-[0058], [63]. Karasiuk discloses in relevant part:

[0063] For us[e] in microdermabrasion, device 10 is positioned so as to place tip 20 in contact with the skin surface to be microabraded and the vacuum source is turned on to establish a vacuum within the system 30. It should be noted here that the order of positioning and turning on the vacuum is not critical as the vacuum can be turned on prior to contacting the tip 20 with skin, since **the vacuum loop will not be closed until such time that opening 20a is sealed by the skin.**

[0064] Upon forming the vacuum loop as described above, the fluid contents in fluid reservoir 70 are drawn through

tube 14 and into device 10 where they flow out of the cannula 16 through openings 16d and are applied to the skin. A targeted area of the skin (which is defined by the perimeter of the opening 20a is drawn up into the tip 20 and a central portion of the targeted area of skin is drawn into contact with abrasive member 24, while portions of the targeted area surrounding the central portion are treated with the fluid contents. As the user or operator of the device 10 glides the tip 20 over the surface of the skin, the targeted area in contact with the abrasive surface 24 is scraped over the abrasive surface wherein microdermabrasion of that portion of the skin is performed. Continued movement of the tip over the skin likewise continues the microdermabrasion of the targeted area, which changes along with the movement of the tip.

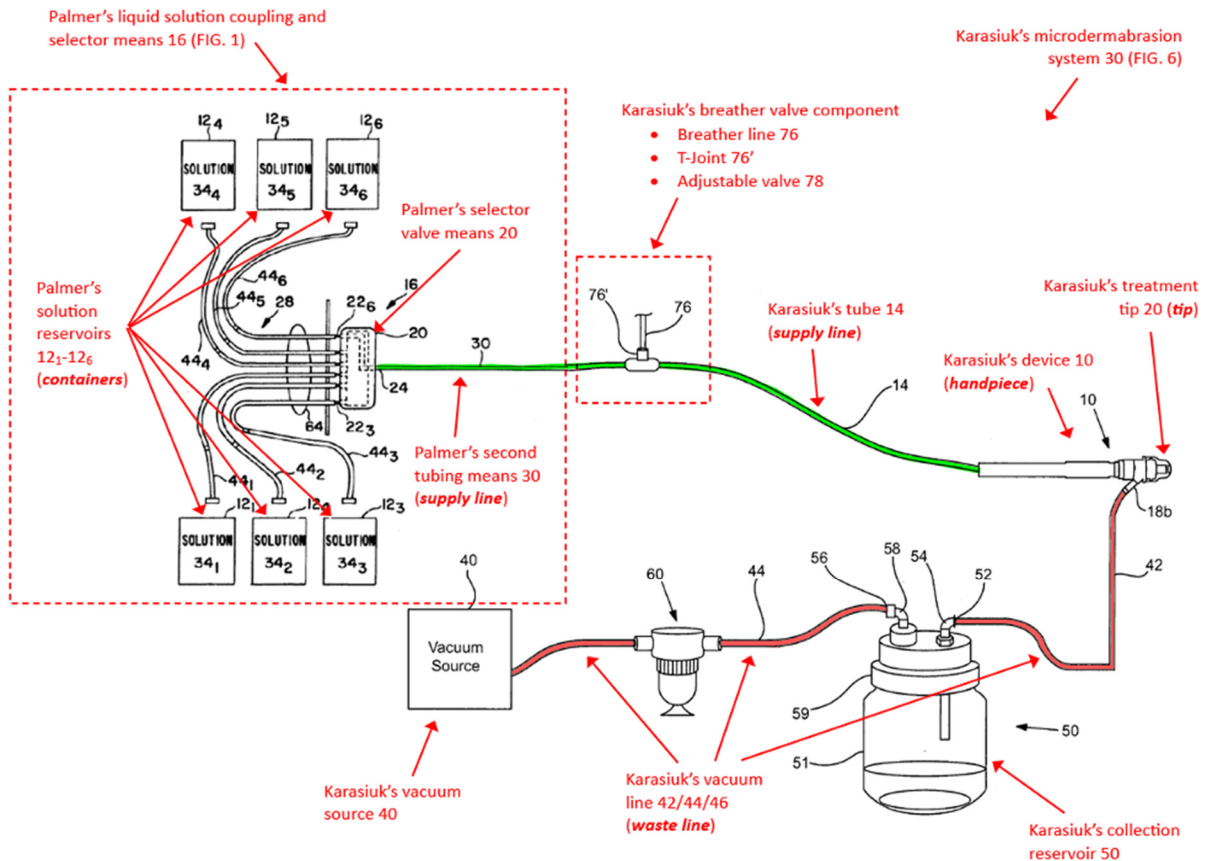
...

[0066] As the flow of the fluids continues out of the vacuum head base and into vacuum line 42, it carries with it the exfoliated skin particles and any other waste that is removed through the microdermabrasion process. Since the fluids surround the abrasive member 24, they are very effective in taking up substantially all of the particles that are loosened during the microdermabrasion process, in contrast with prior art mechanisms having a abrasive tip that can only vacuum up particles from the leading portion of the tip (through a central opening through the abrasive tip), while all of the particles that are loosened or freed up by the trailing side of such a tip (i.e., that portion of the abrasive tip that is behind the central opening with respect to the direction of movement over the skin) are left behind.

EUNSUNG-1004, [0064]-[0066].

148. As I discussed above in § XI.1, a POSITA would have been motivated to use Karasiuk's vacuum source to pump the treatment material and remove waste/debris as originally intended in Karasiuk, in part because Karasiuk's vacuum source can perform the dual function of (1) drawing the treatment material to the

treatment area, and (2) removing waste/debris from the treatment area.



Karasiuk, Modified FIG. 6

149. In the resulting combination of Karasiuk and Palmer, when tip 20 of Karasiuk's device 10 is placed in contact with a skin surface to be microabraded, a vacuum loop is formed, and Karasiuk's vacuum source 40 draws the treatment material from one of Palmer's six reservoirs 12₁-12₆ through Karasiuk's tube 14 into device 10 and draws away from device 10 exfoliated skin particles and other waste material (including used treatment material) through vacuum line 42 into collection reservoir 50 for disposal. EUNSUNG-1004, [0063]-[0066]; *see supra* §

XI.1.

150. Thus, the combined teachings of Karasiuk and Palmer render obvious a vacuum source (e.g., Karasiuk's vacuum source 40) configured to create a vacuum that draws waste material from the handpiece (e.g., Karasiuk's device 10) through the waste line (e.g., Karasiuk's vacuum line 42) for disposal and that draws treatment material (e.g., Palmer's solutions 12₁-12₆) from either the first container (e.g., Palmer's reservoir 12₁) or the second container (e.g., Palmer's reservoir 12₂) to the handpiece (e.g., Karasiuk's device 10) when the tip (e.g., Karasiuk's treatment tip 20) is pressed against skin.

3. Claim 2

[2.pre] The system of claim 1, further comprising:

[2.1] a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece, wherein the flow rate controller is located on the handpiece or on the console; and

151. For the reasons discussed below with respect to claim 3, I believe that the combination of Karasiuk and Palmer renders obvious a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

152. For the reasons discussed below with respect to claim 4, I believe that the combination of Karasiuk and Palmer renders obvious locating the flow rate controller on the handpiece.

153. For the reasons discussed below with respect to claim 5, I believe that

the combination of Karasiuk and Palmer renders obvious locating the flow rate controller on the console.

[2.2] a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

154. For the reasons discussed below with respect to claim 7, I believe that the combination of Karasiuk and Palmer renders obvious a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

4. Claim 3

[3] The system of claim 1, further comprising a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

155. It is my opinion that the Karasiuk-Palmer combination teaches several components for adjusting the flow rate of the first treatment material (e.g., Palmer's solution 12₁) or the second treatment material (e.g., Palmer's solution 12₂) to the handpiece (e.g., Karasiuk's device 10).

156. Generally speaking, in a vacuum-based microdermabrasion system such as Karasiuk-Palmer, the flow rate of a treatment material from a container to a handpiece is directly correlated to, among other things, the level of suction applied to the container by the system's vacuum source. For example, when a container is not connected to a vacuum source, no treatment material will flow from the container to the handpiece—i.e., the flow rate will be zero. When a container is

connected to a vacuum source, the flow rate of the treatment material in the container will vary with the level of suction applied to the container by the vacuum source.

157. A POSITA would have recognized several well-known methods for controlling the level of suction generated by a vacuum source. For example, the vacuum source may be a rotary vane pump, wherein the level of suction generated by the pump may be adjusted by adjusting the speed of the rotor in the pump. Alternatively, the vacuum source may supply a constant level of suction, and the level of suction applied by the vacuum pump to the microdermabrasion system may be adjusted by venting outside air into the vacuum line through a breather line or port. *See, e.g.*, EUNSUNG-1027, 5:42-52; EUNSUNG-1006, [0057].

158. Another well-known method for controlling the flow rate of treatment material to a handpiece is through a flow restrictive device, such as a pinch valve, which operates by reducing the diameter of a tube—thus restricting flow through the tube. *See, e.g.*, EUNSUNG-1007, 8:8-23.

159. Turning now to the teachings of Karasiuk and Palmer, *first*, a POSITA would have understood Palmer's selector valve means 20 as teaching the claimed flow rate controller in the Karasiuk-Palmer system. As discussed with respect to limitation 1.3, Palmer's selector valve means 20 selects which one of reservoirs 12₁-12₆ is connected to the handpiece. EUNSUNG-1005, 8:6-21.

Palmer's selector valve means 20 adjusts the flow rate of the first treatment material or the second treatment material by selecting whether the respective treatment materials are delivered to the handpiece.

160. By way of example, suppose the Karasiuk-Palmer system contains a first container (e.g., Palmer's solution reservoir 12₁) containing a first treatment material (e.g., Palmer's solution 34₁) and a second container (e.g., Palmer's solution reservoir 12₂) containing a second treatment material (e.g., Palmer's solution 34₂). If Palmer's selector valve means 20 is configured to place Karasiuk's device 10 in fluid communication with the first container, the first treatment material would be drawn from the first container, through Karasiuk's device 10, and then into Karasiuk's collection reservoir 50. The first treatment material would flow to Karasiuk's device 10 at a certain rate (depending on, among other things, the level of suction applied to the container). And, in this instance, the flow rate of the second treatment material to Karasiuk's device 10 would be zero because it is not in communication with Karasiuk's vacuum source 40.

161. If the configuration of Palmer's selector valve means 20 is adjusted to place Karasiuk's device 10 in fluid communication with the second container, then the second treatment material would be drawn from the second container, through Karasiuk's device 10, and then into Karasiuk's collection reservoir 50. In this instance, the second treatment material would flow to Karasiuk's device 10 at a

certain rate (depending on, among other things, the level of suction applied to the container through), while the flow rate of the first treatment material would then be zero.

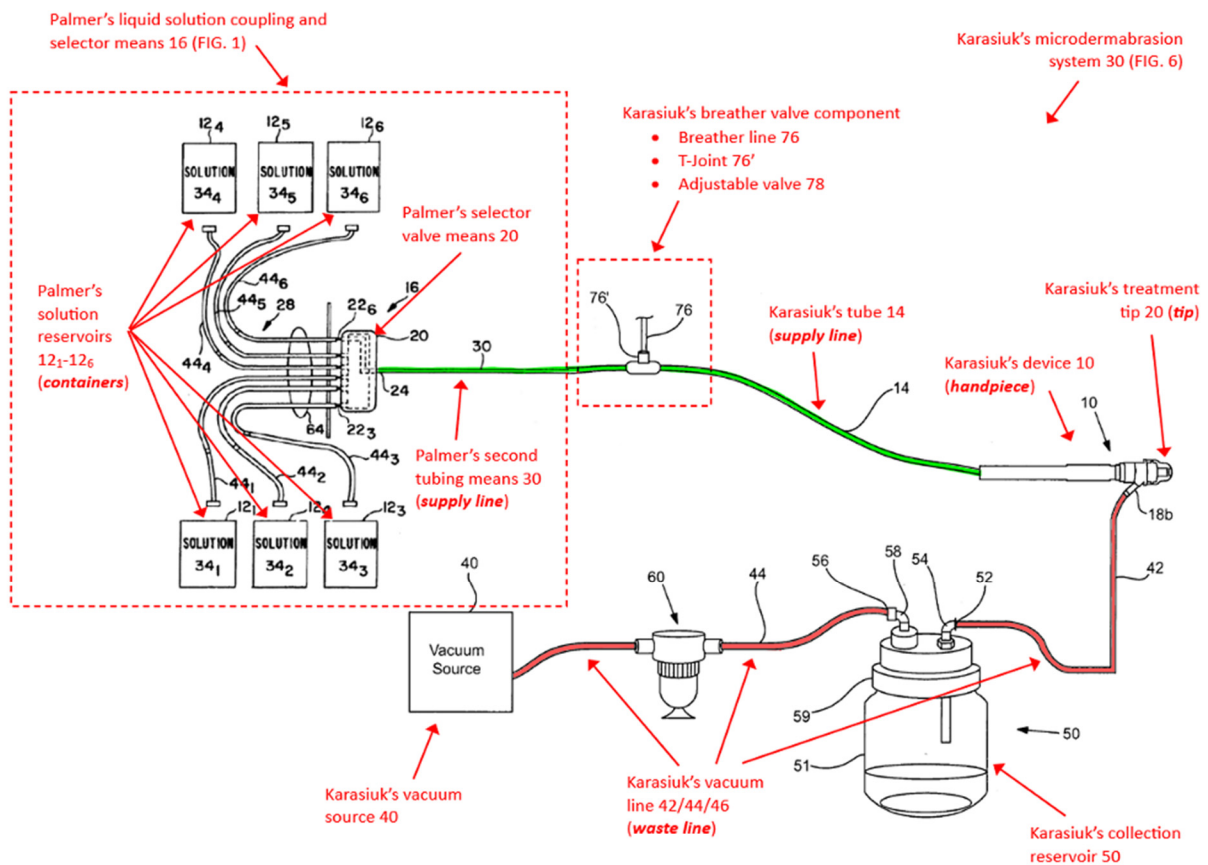
162. Because Palmer's selector valve means 20 adjusts the flow rate of the first treatment material or the second treatment material to Karasiuk's device 10, a POSITA would have recognized Palmer's selector valve means 20 as teaching the claimed flow rate controller.

163. *Second*, a POSITA would have understood Karasiuk's breather valve component as teaching the claimed flow rate controller in the Karasiuk-Palmer system. Karasiuk teaches a breather-valve-type flow rate controller, comprising breather line 76, T-joint 76', and adjustable valve 78. EUNSUNG-1004, [0059]. Specifically, Karasiuk discloses in relevant part:

[0059] Tube 14 extends from the proximal end of the microdermabrasion device 10, and connects with output 72 of fluid reservoir 70 via elbow 74, for example. **A breather line 76 may be connected inline via T-joint 76', for example, or other interconnection, and includes an adjustable valve 78 or other means for varying an amount of air that is allowed into the tube 14. This feature not only allows the amount of vacuum to be adjusted for a given fluid, but allows fluids having different viscosities to be applied at the same vacuum level, since different viscosities will require varying amounts of air to be inletted through the breather line, to give a constant vacuum level.** Alternatively, a breather line or input with adjustment valve may be located on elbow 74 or directly on manifold cover 79.

Id.

164. In the Karasiuk-Palmer system, Karasiuk's breather valve (i.e., breather line 76, T-joint 76', and adjustable valve 78) is connected to Karasiuk-Palmer's supply line (e.g., Karasiuk's tube 14 or Palmer's second tubing means 30). Karasiuk's breather valve is depicted below in modified Karasiuk FIG. 6. Karasiuk does not explicitly disclose where the breather valve is located, apart from being somewhere on tube/fluid delivery line 14. *See id.*, [0059], FIG.6.



Karasiuk, Modified FIG. 6

165. A POSITA would have readily appreciated that, in the Karasiuk-

Palmer combination, Karasiuk's adjustable valve 78 would adjust the flow rate of the treatment material from the container selected by Palmer's selector valve means 20 to Karasiuk's device 10 by varying the amount of air allowed into Karasiuk-Palmer's supply line through Karasiuk's breather line 76. Allowing air to vent into Karasiuk-Palmer's vacuum loop before reaching the selected container would adjust the level of suction applied to the container and thus the flow rate of the treatment material from the selected container to Karasiuk's device 10. EUNSUNG-1004, [0059].

166. **Third**, a POSITA would have understood Karasiuk's disclosure of an additional "valve or other flow control mechanism" as teaching the claimed flow rate controller in the Karasiuk-Palmer system. Karasiuk describes a second "valve or other flow control mechanism [that] may be provided in fluid delivery line 14 to control the amount of liquid passing through the line." EUNSUNG-1004, [0059]. Karasiuk explains that this "valve or other flow control mechanism" (hereinafter "second valve") may be provided in addition or as an alternative to the breather valve component (i.e., adjustable valve 78, breather line 76, T-joint 76'). *Id.*

167. Specifically, Karasiuk discloses in relevant part:

[0059] Tube 14 extends from the proximal end of the microdermabrasion device 10, and connects with output 72 of fluid reservoir 70 via elbow 74, for example. A breather line 76 may be connected inline via T-joint 76', for example, or other interconnection, and includes an adjustable valve 78 or other means for varying an amount of air that is allowed into the tube

14. This feature not only allows the amount of vacuum to be adjusted for a given fluid, but allows fluids having different viscosities to be applied at the same vacuum level, since different viscosities will require varying amounts of air to be inletted through the breather line, to give a constant vacuum level. Alternatively, a breather line or input with adjustment valve may be located on elbow 74 or directly on manifold cover 79. **Still further, a valve or other flow control mechanism may be provided in the fluid delivery line 14 to control the amount of liquid passing through the line. This feature can be provided alternatively, or in addition to the breather line discussed above.**

Id.

168. Karasiuk does not explicitly disclose where the second valve is located, apart from being somewhere on tube/fluid delivery line 14. *See id.*, [0059], FIG. 6.

169. A POSITA would have readily appreciated that, in the Karasiuk-Palmer combination, Karasiuk's second valve would adjust the flow rate of the treatment material from the container selected by Palmer's selector valve means 20 to Karasiuk's device 10 by "controlling the amount of liquid passing through" Karasiuk-Palmer's supply line. EUNSUNG-1004, [0059]. A POSITA would have appreciated that Karasiuk's second valve could take the form of a variety of well-known valves, including, for example, a ball valve, globe valve, needle valve, or pinch valve.

170. For the reasons above, the combined teachings of Karasiuk and Palmer render obvious a flow rate controller (e.g., Palmer's selector valve means

20, Karasiuk's breather valve, or Karasiuk's second valve) to adjust a flow rate of the first treatment material (e.g., Palmer's solution 12₁) or the second treatment material (e.g., Palmer's solution 12₂) to the handpiece (e.g., Karasiuk's device 10).

5. Claim 4

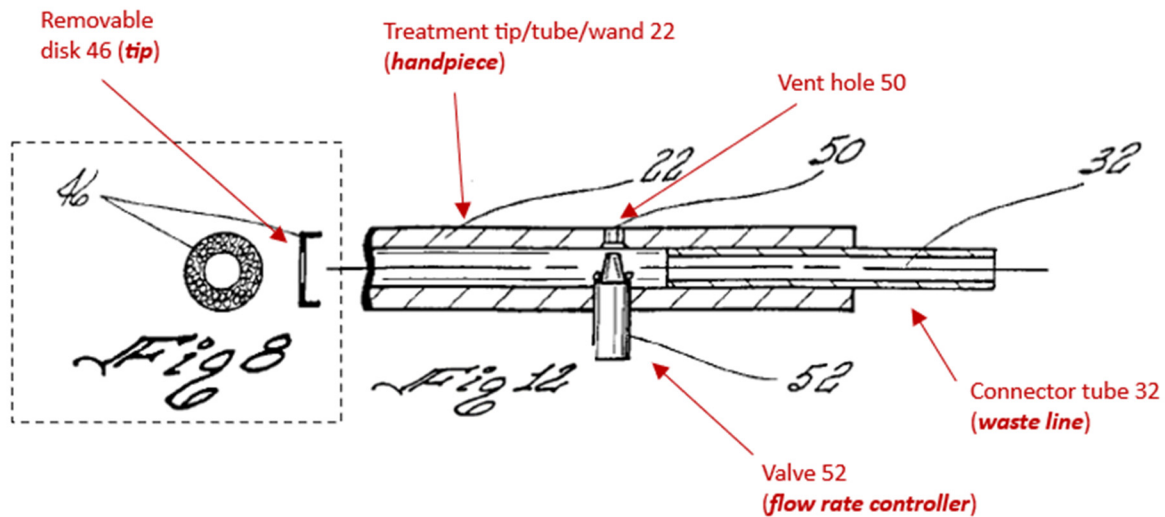
[4] The system of claim 3, wherein the flow rate controller is located on the handpiece.

171. As discussed above with respect to claim 3, I believe that a POSITA would have understood Karasiuk's breather valve and second valve as rendering obvious the claimed flow rate controller. Apart from being somewhere on fluid delivery line/tube 14, Karasiuk does not explicitly disclose where either valve is located. *See* EUNSUNG-1004, [0059].

172. It is my opinion that a POSITA would have found it obvious to locate Karasiuk's breather valve or second valve on Karasiuk-Palmer's supply line (e.g., Karasiuk's tube 14) as it travels through the handle 12 of device 10. Several reasons lead me to believe that a POSITA would have found locating Karasiuk's breather valve or second valve on Karasiuk's device 10.

173. ***First***, I believe that locating Karasiuk's breather valve or second valve on Karasiuk's device 10 would have been an obvious design choice in view of the knowledge of a POSITA. A POSITA would have known that similar prior art handpieces include a flow rate controller. For example, Waldron includes a flow control valve 52 and corresponding vent hole 50 on the handpiece of a

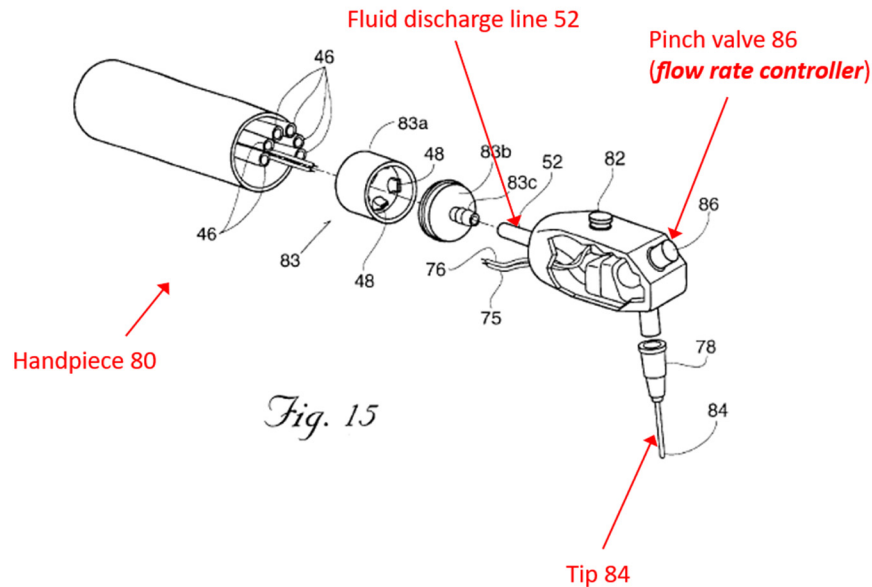
dermabrasion system. EUNSUNG-1033, 5:41-52; *see* § X.3. A POSITA would have understood Waldron's flow control valve 52 and vent hole 50 as directly analogous to Karasiuk's adjustable valve 78 and breather line 76—both control the level of suction generated by a vacuum source by allowing outside air to vent into the vacuum loop.



Waldron, FIG. 3 (annotated)

174. As another example, Pond includes a pinch valve 86 located on a dental handpiece 80 to regulate the fluid discharge out of tip 84. EUNSUNG-1007, 8:8-24. A POSITA would have understood Pond's pinch valve 86 as directly analogous to Karasiuk's second valve—both control “the amount of liquid passing through [a fluid delivery] line.” EUNSUNG-1005, [0059]; *see* EUNSUNG-1007, 8:8-24. Given that Karasiuk-Palmer teaches the use of flexible plastic tubes (EUNSUNG-1004, [0045]) and the relatively low level of suction in the system, a

pinch valve like Pond's pinch valve 86 would have been one obvious implementation of Karasiuk's second valve.



Pond, FIG. 15 (annotated)

175. Thus, a POSITA would have appreciated that locating Karasiuk's breather valve or second valve on Karasiuk's device 10 would not result in any difference in the function of the Karasiuk-Palmer system, would be well within the knowledge and skill of a POSITA, and would yield expected results.

176. **Second**, I believe that it would have been obvious to a POSITA to try locating Karasiuk's breather valve or second valve on Karasiuk's device 10. In the Karasiuk-Palmer combination, a POSITA would have identified three predictable locations along Karasiuk-Palmer's supply line for Karasiuk's breather valve or second valve: (1) at a component in the console where the supply line emanates

from—similar to Palmer’s selector valve means 20 (EUNSUNG-1005, 5:10-22, 7:49-8:5, 8:6-21), (2) at some position along the supply line as it traverses between the console and the handpiece—e.g., as depicted in Karasiuk’s FIG. 6, or (3) contained somewhere within the handpiece itself—e.g., similar to Waldron’s valve 52 (EUNSUNG-1033, 5:42-52, FIG. 12) and Pond’s pinch valve 86 (EUNSUNG-1007, 8:8-24, FIG. 15). Given these options, I believe that it would have been obvious to a POSITA to try locating Karasiuk’s breather valve or second valve on Karasiuk’s device 10.

177. **Third**, I believe that a POSITA would have been motivated to locate Karasiuk’s breather valve or second valve on Karasiuk’s device 10 to allow an operator to more easily adjust the flow rate of the treatment material while performing a microdermabrasion procedure. A POSITA would have appreciated that it is more accessible and convenient for an operator to adjust a flow rate controller mounted on a device that the operator is already holding than having to reach to a flow rate controller mounted in another location (e.g., on a console). *See, e.g., EUNSUNG-1033, 5:51-52 (“The [flow control] valve 52 can be configured to be a simple on/off control or variable so that suction can be readily adjusted by the operator while performing the procedure.”).*

178. A POSITA would have recognized the desirability of being able to easily control the flow rate of the treatment material while performing a

microdermabrasion treatment because different treatment areas and patients may require varying levels of suction and treatment material to receive an effective treatment. *See, e.g.*, EUNSUNG-1031, 4 (“Certain areas, including scars or hyperpigmented skin, may require more aggressive treatment with additional passes, increased crystal flow, or greater vacuum.”). In my opinion, a POSITA would have understood that locating the flow rate controller on the handpiece is more convenient for the operator than placing it on a console and results in faster, more effective, and safer treatments.

179. Additionally, I believe that a POSITA would have appreciated the advantage of locating Karasiuk’s breather valve or second valve in or on a structure, like Karasiuk’s device 10, to provide structural support for the valve and prevent fouling and damage.

180. For the reasons above, a POSITA would have understood the combined teachings of Karasiuk and Palmer as rendering obvious locating a flow rate controller (e.g., Karasiuk’s breather valve or second valve) on a handpiece (e.g., Karasiuk’s device 10).

6. Claim 5

[5] The system of claim 3, wherein the flow rate controller is located on the console.

181. As discussed above with respect to claim 3, I believe that a POSITA would have understood Palmer’s selector valve means 20 as rendering obvious the

FIG. 4

Selector valve means 20
(flow rate controller)

Front panel 92

Rotatable core 72

183. Thus, a POSITA would have understood the combined teachings of Karasiuk and Palmer as rendering obvious locating a flow rate controller (e.g., Palmer's selector valve means 20) on a console (e.g., Palmer's mobile cart 170).

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the claimed flow rate controller in the Karasiuk-Palmer combination. Apart from being somewhere on fluid delivery line/tube 14, Karasiuk does not explicitly disclose where the either valve is located. *See* EUNSUNG-1004, [0059].

185. In my opinion, it would have been obvious to a POSITA to locate Karasiuk's breather valve or second valve on Palmer's mobile cart 170 for three reasons. **First**, I believe that locating Karasiuk's breather valve on Palmer's mobile cart 170 would have been an obvious design choice in view of the knowledge of a POSITA. Given that Palmer locates other components that interface with and control the flow of treatment material through the supply line on Palmer's mobile cart 170 (e.g., Palmer's selector valve means 20), locating Karasiuk's breather valve on Palmer's mobile cart 170 (e.g., in control unit enclosure 35) yields expected results without altering the function of the Karasiuk-Palmer system. Moreover, using a console to house a flow rate controller was also known and within the general knowledge of a POSITA. *See, e.g.*, EUNSUNG-1028, FIG. 9. Indeed, Karasiuk itself suggests locating the breather valve on the container side of tube 14. EUNSUNG-1004, [0059] ("Alternatively, a breather line or input with adjustment valve may be located on elbow 74 or directly on manifold cover 79 [of reservoir 70].").

186. **Second**, I believe that it would have been obvious to a POSITA to try locating Karasiuk's breather valve on Palmer's mobile cart 170. In the Karasiuk-

Palmer combination, a POSITA would have identified three predictable locations along Karasiuk-Palmer's supply line for Karasiuk's breather valve or second valve: (1) at a component in the console where the supply line emanates from—similar to Palmer's selector valve means 20 (EUNSUNG-1005, 5:10-22, 7:49-8:5, 8:6-21), (2) at some position along the supply line as it traverses between the console and the handpiece—e.g., as depicted in Karasiuk's FIG. 6, or (3) contained somewhere within the handpiece itself—e.g., similar to Waldron's valve 52 (EUNSUNG-1033, 5:42-52, FIG. 12) and Pond's pinch valve 86 (EUNSUNG-1008, 8:8-24, FIG. 15). Given these options, I believe that it would have been obvious to a POSITA to try locating Karasiuk's breather valve or second valve on Palmer's mobile cart 170.

187. **Third**, I believe that a POSITA would have been motivated to locate Karasiuk's breather valve or second valve on Palmer's mobile cart 170 for added portability and organization. Karasiuk itself suggests locating a flow rate controller on/near the supply container. EUNSUNG-1004, [0059] ("Alternatively, a breather line or input with adjustment valve may be located on elbow 74 or directly on manifold cover 89 [of fluid reservoir 70]."). As I discussed with respect to limitation 1.1, using a console to house similar medical devices was well-known and would have been within a POSITA's general knowledge. Moreover, using a console to house a flow rate controller was also known and within the general knowledge of a POSITA. *See, e.g.*, EUNSUNG-1028, FIG. 9. A POSITA would

have had a reasonable expectation of success in locating Karasiuk's breather valve or second valve on Palmer's mobile cart 170, as it would constitute the use of a known technique to improve similar devices in the same way.

188. For the reasons above, a POSITA would have understood the combined teachings of Karasiuk and Palmer as rendering obvious locating a flow rate controller (e.g., Palmer's selector valve means 20, Karasiuk's breather valve, or Karasiuk's second valve) on a console (e.g., Palmer's mobile cart 170).

7. Claim 7

[7] The system of claim 1, further comprising a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

189. It is my opinion that the Karasiuk-Palmer combination renders obvious a user input device (e.g., Palmer's selector knob 78) to select the first treatment material (e.g., Palmer's solution 12₁) or the second treatment material (e.g., Palmer's solution 12₂) for delivery to the handpiece (e.g., Karasiuk's device 10).

190. As discussed in § X.2, Palmer includes a selector valve means 20 for fluidly coupling a handpiece with a selected solution reservoir. EUNSUNG-1005, 5:1-9. Palmer discloses in relevant part:

The liquid solution coupling and selector means 16 include **selector valve means 20 having a plurality of inputs 22**, an output 24, and means for coupling a selected one of the inputs 22 to the output 24, first tubing means 28 for fluidly coupling each

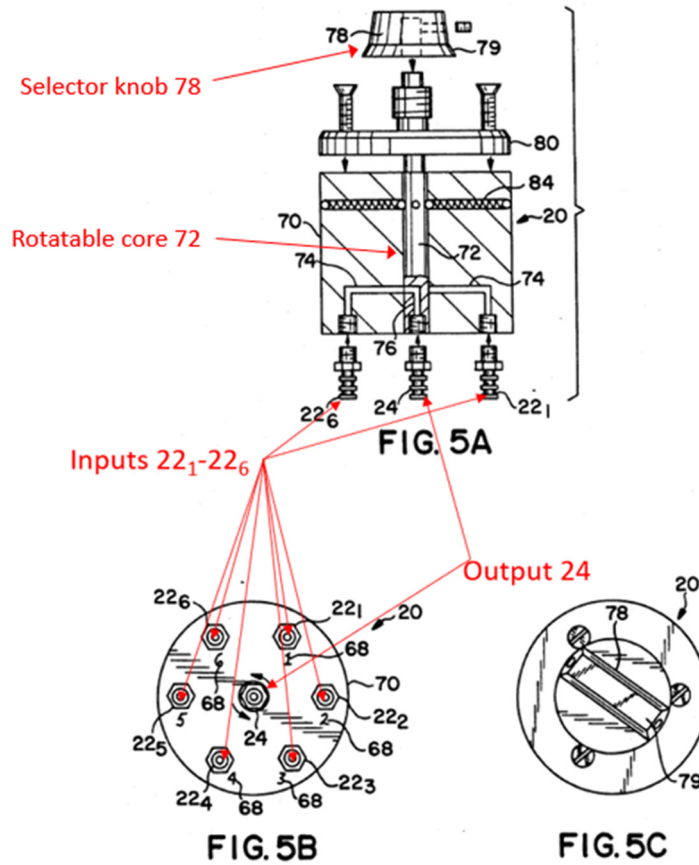
of the solutions in a respective reservoir 12 to a respective one of the inputs 22 of the selector valve inputs 22, **and second tubing means 30 for fluidly coupling the output 24 of the selector valve means to the handpiece means 14.**

EUNSUNG-1005, 5:1-9.

191. Palmer further describes the selector valve means as follows:

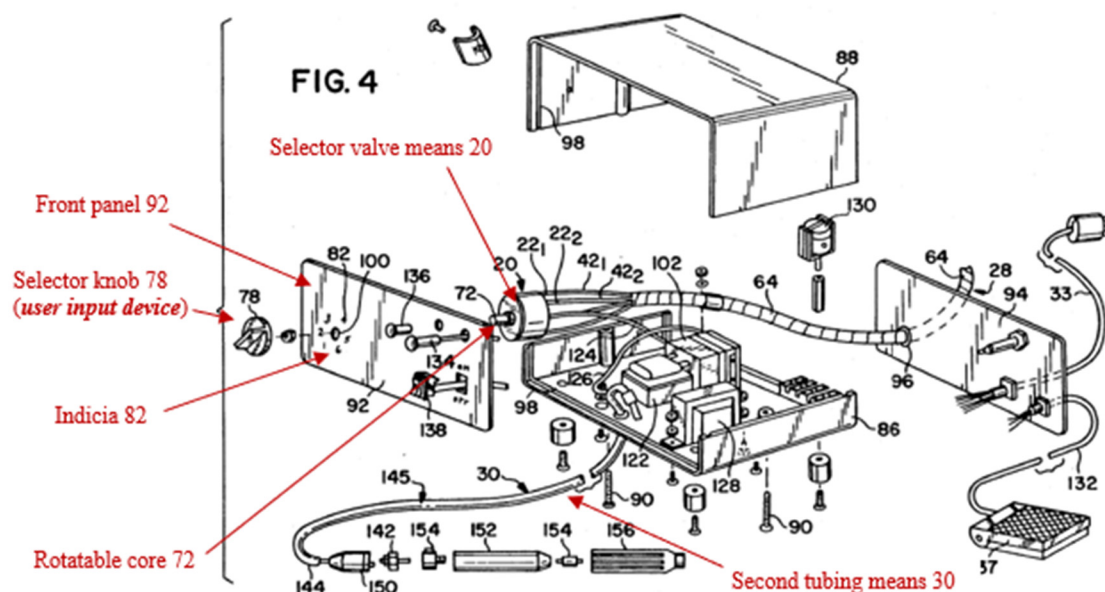
Referring to FIG. 5, selector valve means 20 comprises a main body 70 having a central cylinder core or stem 72 rotatably mounted therein. Six liquid inlet passages 74 are formed through the body 70, each inlet passage opening into a respective input port 22 at its outer end, and at its inner end, into the bore which receives the rotatable core 72 in a plane common with the inner ends of the other inlet passages 74. 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. **The selector valve means also comprises a selector knob 78 which is fastened to the end region of core 72 which protrudes through a face plate 80 of selector valve 20.**

EUNSUNG-1005, 8:6-21.



Palmer, FIG. 5A-C

192. Palmer discloses a “selector knob 78,” located on front panel 92 of control unit enclosure 35, which is fastened to rotatable core 72 of selector valve means 20. EUNSUNG-1005, 7:49-8:53. A user rotates selector knob 78 to align with one of the indicia 82 on front panel 92 corresponding with one of the solution reservoirs 12₁-12₆ (containing solutions 34₁-34₆, respectively) to connect the corresponding solution reservoir with second tubing means 30.



Palmer, FIG. 4 (annotated)

193. In my opinion, a POSITA would have understood Palmer's selector knob 78 as a user input device to select the first treatment material (e.g., solution 12₁) or the second treatment material (e.g., solution 12₂). Thus, the combined teachings of Karasiuk and Palmer render obvious a user input device (e.g., Palmer's selector knob 78) to select the first treatment material (e.g., Palmer's solution 12₁) or the second treatment material (e.g., Palmer's solution 12₂) for delivery to the handpiece (e.g., Karasiuk's device 10).

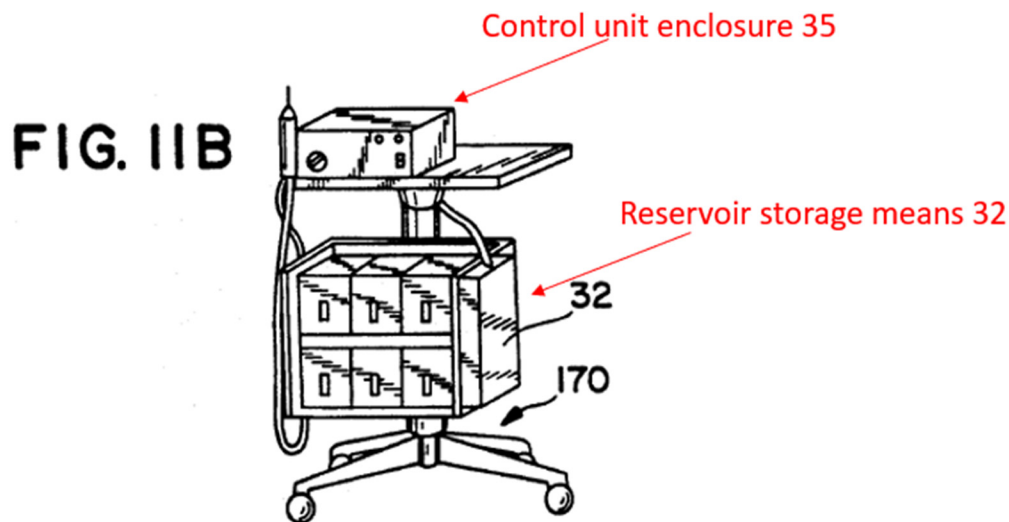
8. Claim 9

[9] The system of claim 7, wherein the user input device is positioned on the console.

194. As discussed above with respect to claim 7, I believe that a POSITA would have understood Palmer's selector knob 78 as rendering obvious the

claimed user input device. The Karasiuk-Palmer combination also renders obvious positioning a user input device (e.g., Palmer's selector knob 78) on a console (e.g., Palmer's mobile cart 170).

195. Palmer discloses that selector knob 78 is positioned on the front panel of control unit enclosure 35. EUNSUNG-1005, 8:31-56, FIG. 4. As explained with respect to limitation 1.1, Palmer's control unit enclosure 35 is positioned on Palmer's mobile cart 170. EUNSUNG-1005, 9:58-10:16, FIG. 11B.



Palmer, FIG. 11B (annotated)

196. Thus, a POSITA would have understood the combined teachings of Karasiuk and Palmer as rendering obvious a user input device (e.g., Palmer's selector knob 78) positioned on a console (e.g., Palmer's mobile cart 170).

9. Claim 20

197. Claim 20 claims similar subject matter recited in claim 1 and claim 2,

which in turn claims similar subject matter recited in claims 3-5 and 7.

[20.pre] A skin treatment system, comprising:

198. For the reasons discussed above with respect to limitation 1.pre, I believe that the combination of Karasiuk and Palmer renders obvious a skin treatment system.

[20.1] a console configured to receive a first container containing a first treatment material and a second container containing a second treatment material;

199. For the reasons discussed above with respect to limitation 1.1, I believe that the combination of Karasiuk and Palmer renders a console configured to receive a first container containing a first treatment material and a second container containing a second treatment material.

[20.2] a handpiece configured to couple to a tip that can be pressed against skin to perform skin treatment;

200. For the reasons discussed above with respect to limitation 1.2, I believe that the combination of Karasiuk and Palmer renders obvious a handpiece configured to couple to a tip that can be pressed against skin to perform skin treatment.

[20.3] a supply line connected between the handpiece and the console for sequentially delivering treatment material to the handpiece from the first container or the second container;

201. For the reasons discussed above with respect to limitation 1.3, I believe that the combination of Karasiuk and Palmer renders obvious a supply line

connected between the handpiece and the console for sequentially delivering treatment material to the handpiece from the first container or the second container.

[20.4] a waste line connected between the handpiece and the console;

202. For the reasons discussed above with respect to limitation 1.4, I believe that the combination of Karasiuk and Palmer renders obvious a waste line connected between the handpiece and the console.

[20.5] a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is pressed against skin;

203. For the reasons discussed above with respect to limitation 1.5, I believe that the combination of Karasiuk and Palmer renders obvious a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is pressed against skin.

[20.6] a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece, wherein the flow rate controller is located on the handpiece or on the console; and

204. For the reasons discussed above with respect to claim 3, I believe that the combination of Karasiuk and Palmer renders obvious a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

205. For the reasons discussed above with respect to claim 4, I believe that the combination of Karasiuk and Palmer renders obvious locating the flow rate controller on the handpiece.

206. For the reasons discussed above with respect to claim 5, I believe that the combination of Karasiuk and Palmer renders obvious locating the flow rate controller on the console.

[20.7] a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

207. For the reasons discussed above with respect to claim 7, I believe that the combination of Karasiuk and Palmer renders obvious a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

XII. [GROUND 1B] – Karasiuk, Palmer, and Waldron

1. Claims 2, 4, and 20

208. The combined teachings of Karasiuk, Palmer, and Waldron render obvious claims 2, 4, and 20 for the same reasons discussed above regarding Karasiuk and Palmer—i.e., it would have been obvious to a POSITA to locate Karasiuk’s breather valve or second valve on Karasiuk’s device 10.

209. It is my opinion that the combination of Karasiuk, Palmer, and Waldron further renders obvious claims 2, 4, and 20 based on Waldron’s teachings. As discussed in § X.3, Waldron discloses a handpiece-mounted flow control valve

52 with a corresponding vent hole 50 for adjusting the level of suction in a vacuum line. A POSITA would have found it obvious to modify Karasiuk's device 10 to include Waldron's flow control valve 52 and vent hole 50 in two ways.

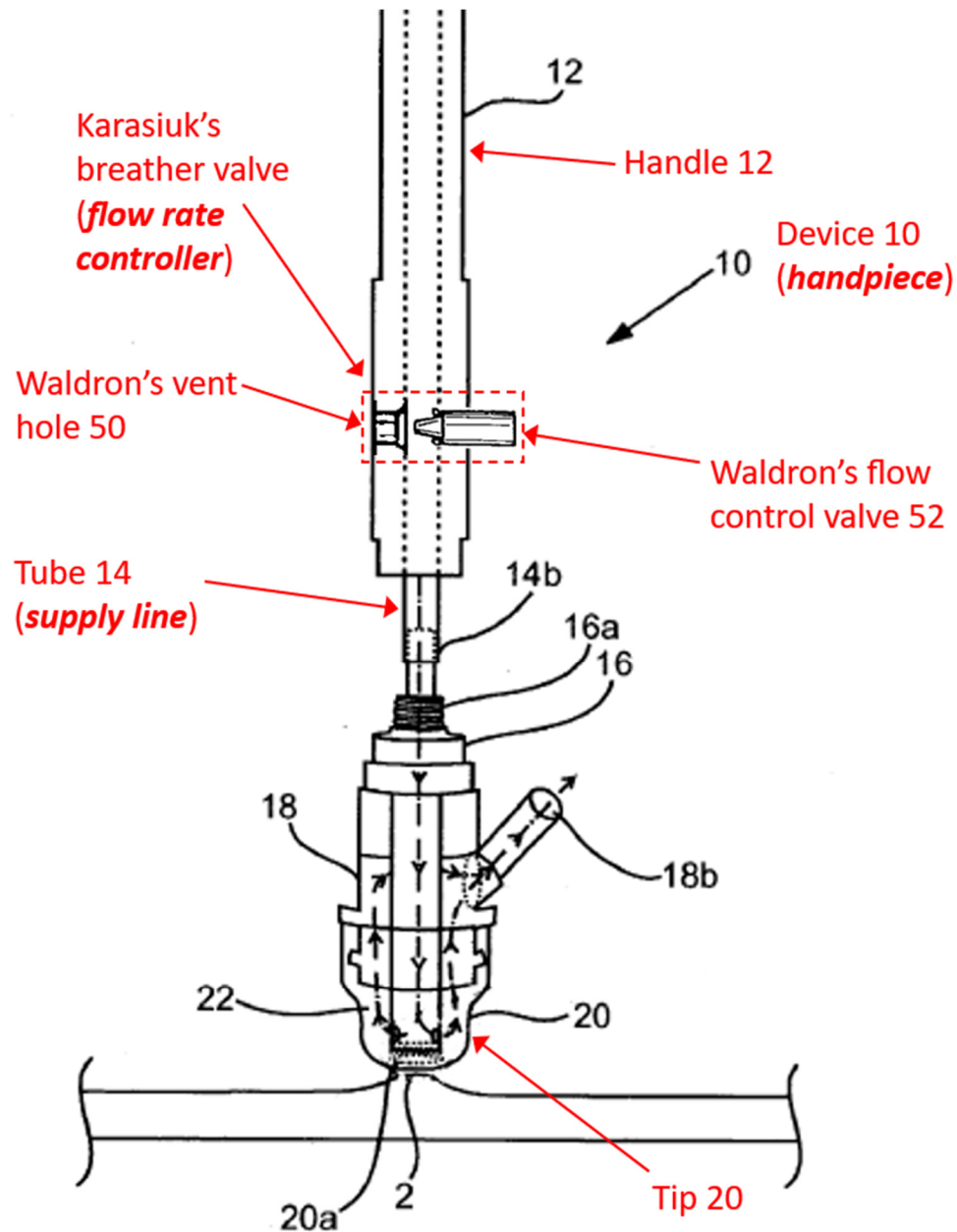
210. *First*, a POSITA would have found it obvious to include Waldron's flow control valve 52 and vent hole 50 on Karasiuk-Palmer's supply line (e.g., Karasiuk's tube 14) as it travels through handle 12 of Karasiuk's device 10. As discussed in § XI.5, Karasiuk provides a breather valve component comprising breather line 76, T-joint 76', and adjustable valve 78, which Karasiuk explains "may be connected inline" with tube 14. EUNSUNG-1005, [0059]; FIG. 6. But Karasiuk does not explicitly disclose where along tube 14 the breather valve component is located. As discussed above in § XI.5, a POSITA would have been motivated and found it obvious to include a flow rate controller on a handpiece. Waldron's handpiece-mounted flow rate controller (i.e., flow control valve 52 and vent hole 50) was one such method known in the art.

211. In the Karasiuk-Palmer-Waldron combination, a POSITA would have found it obvious to replace Karasiuk's breather line 76, T-joint 76', and adjustable valve 78 with Waldron's handpiece-mounted flow control valve 52 and vent hole 50. For example, a POSITA would have found it obvious to include Karasiuk's breather valve in the form of Waldron's handpiece-mounted flow control valve 52 and vent hole 50 on Karasiuk-Palmer's supply line (e.g., Karasiuk's tube 14) as it

travels through handle 12 of Karasiuk's device 10. An example of this

implementation of Karasiuk's breather valve is depicted below in Modified

Karasiuk FIG. 1A.



Karasiuk, Modified FIG. 1

212. In my opinion, a POSITA would have had a reasonable expectation of success in replacing Karasiuk's adjustable valve 78, breather line 76, and T-Joint 76' with Waldron's handpiece-mounted flow control valve 52 and vent hole 50 in the Karasiuk-Palmer system given that Karasiuk teaches a breather valve component "for varying an amount of air that is allowed into the tube 14" and Waldron's handpiece-mounted flow control valve 52 was a similar breather valve component known in the art. EUNSUNG-1004, [0059]; EUNSUNG-1033, 5:41-52.

213. In my opinion, a POSITA would have understood that replacing Karasiuk's breather line 76, T-joint 76', and adjustable valve 78 with Waldron's handpiece-mounted flow control valve 52 and vent hole 50 would have been the simple substitution of one known element (e.g., Waldron's valve and vent hole) for another (e.g., Karasiuk's valve and breather line) to achieve predictable results—i.e., a handpiece-mounted breather valve for adjusting the level of suction applied to the treatment containers and thus the flow rate of a treatment material delivered to a handpiece. This combination similarly reflects the use of a known technique to improve similar devices in the same way. Moreover, the combination is merely an application of known technique to a device ready for improvement.

214. In addition to Waldron disclosing that flow control valve 52 is located on a handpiece (i.e., treatment tip/tube/wand 22), in the Karasiuk-Palmer-Waldron

combination described above, a POSITA would have found it obvious to locate Waldron's flow control valve 52 on Karasiuk's device 10 for similar reasons to those discussed above in § XI.5.

215. Thus, a POSITA would have recognized the combined teachings of Karasiuk, Palmer, and Waldron as rendering obvious a flow rate controller (e.g., Waldron's flow control valve 52 and vent hole 50) located on a handpiece (e.g., on handle 12 of Karasiuk's device 10).

216. ***Second***, a POSITA would have found it obvious to include Waldron's flow control valve 52 and vent hole 50 on the return/waste side of Karasiuk's device 10 (e.g., at port 18b). A POSITA would have understood that a breather valve such as Waldron's flow control valve 52 and vent hole 50 or Karasiuk's adjustable valve 78 and breather line 76 affects the air flow through all components in a vacuum loop that are attached upstream from the flow rate controller by allowing air to vent into the line (through, e.g., Karasiuk's breather line 76 or Waldron's vent hole 50), thus bypassing the upstream components. A note on nomenclature: A POSITA would refer to the terms "upstream" and "downstream" analogously to flow in a stream or river. Upstream is construed to be proximal to the source of the flow, e.g. a reservoir; downstream is construed to proximal to the sink or outlet of the flow. As applied to a dermabrasion device, upstream therefore refers to locations and/or components which reside up the flow path from the

handpiece, and conversely, downstream refers to locations and/or componentry which reside down the flow path from the handpiece.

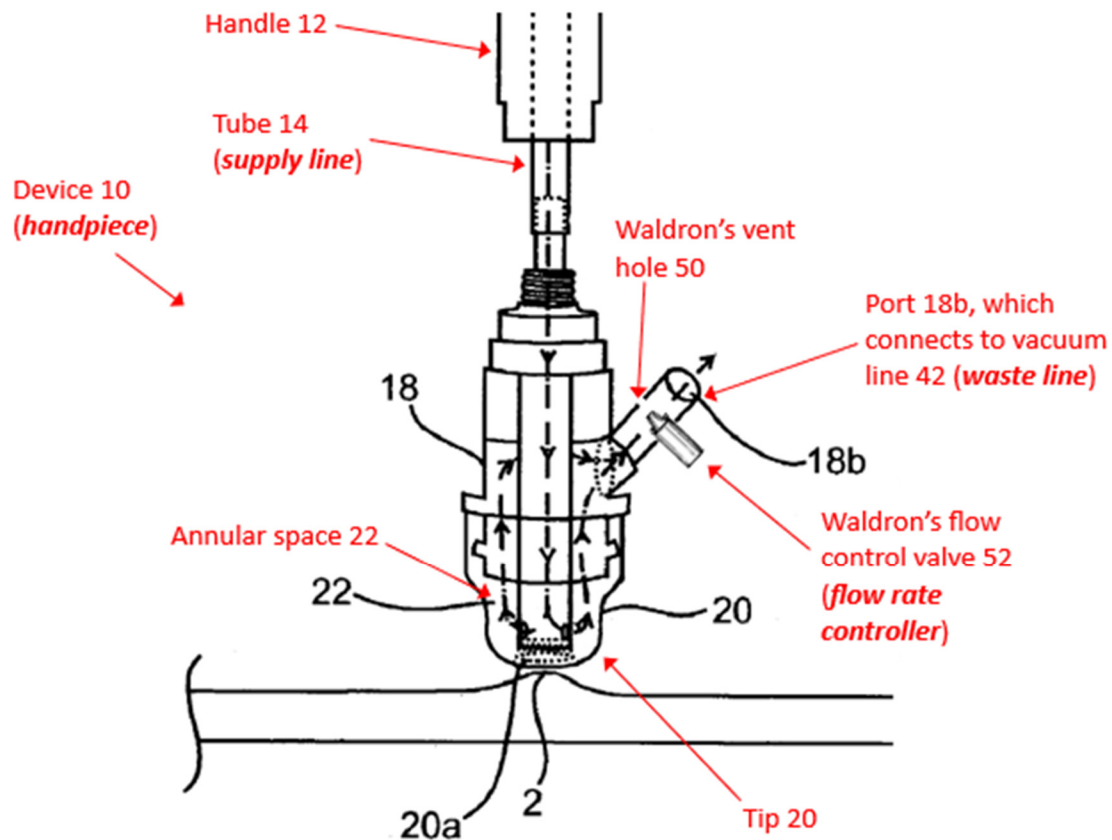
217. Unlike Karasiuk's breather valve or second valve, in Waldron, flow control valve 52 and vent hole 50 are located at a point in the vacuum loop downstream from the treatment tip, and thus adjusts the level of suction at the treatment tip and *before* reaching the treatment area. EUNSUNG-1005, 5:41-52. Thus, locating a flow rate controller at this point in the system allows the operator to adjust the level of suction applied to the treatment area. EUNSUNG-1005, 5:41-52.

218. A POSITA would have appreciated that it is desirable to control the level of suction applied to a treatment area while performing a microdermabrasion procedure because different treatment areas and patients may require varying levels of suction and treatment material to receive an effective treatment. *See* EUNSUNG-1031, 4 ("Certain areas, including scars or hyperpigmented skin, may require more aggressive treatment with additional passes, increased crystal flow, or greater vacuum."). As I explained in § VII.A, reducing the level of suction may be necessary around the eyes and other delicate areas of the face and in accordance with the patient's tolerance. EUNSUNG-1013, 85-86; *see also* EUNSUNG-1029, 4:50-52 ("The physician will learn from experience how to balance the pressure level to attain the desired level of suction against the patient's skin."). Indeed,

Karasiuk itself recognizes that having a range of suction levels is advantageous.

EUNSUNG-1004, [0058] (“[A] vacuum in the range of about 2 to 14 psi is generally used during a procedure, depending upon the skin condition of the person being treated.”). But Karasiuk does not explicitly disclose a mechanism to vary the level of suction in the system before reaching the treatment tip.

219. In my opinion, a POSITA would have been motivated to combine Waldron’s handpiece-mounted flow control valve 52 with the Karasiuk-Palmer system to allow an operator to adjust the level of suction in the treatment tip. For example, a POSITA would have found it obvious to modify Karasiuk’s device 10 to include Waldron’s handpiece-mounted flow control valve 52 and corresponding vent hole 50 at a point before reaching Karasiuk’s treatment tip 20 (e.g., port 18b) so that Waldron’s flow control valve 52 may adjust the level of suction in the treatment tip and thus the level of suction applied to the skin surface to be treated. An example of the Karasiuk-Palmer-Waldron combination is illustrated below in Modified Karasiuk FIG. 1A.



Karasiuk, Modified FIG. 1

220. In the above example, Karasiuk's port 18b, which connects to Karasiuk's vacuum line 42, is modified to include Waldron's handpiece-mounted flow control valve 52 and vent hole 50. This modification would allow an operator to adjust the level of suction in the annular space 22 of tip 20 and thus the level of suction applied to the treatment area.

221. In the Karasiuk-Palmer-Waldron combination, Waldron's flow control valve 52 and vent hole 50 could be used alone or in conjunction with Karasiuk's breather valve or second valve to fine tune both the level of suction and

the amount of treatment material delivered to the treatment area. For example,

Ramey discloses a microdermabrasion system with two flow rate controllers:

abrasive concentration controller 128 and vacuum level controller 119.

EUNSUNG-1028, 13:55-24; FIG. 8. Abrasive concentration controller 128 is

located on the supply side of hand piece 118 (i.e., upstream of hand piece 118) and

“mix[es] ambient air into the abrasive-laden air coming from feed device 114 and

leading toward hand piece 118.” *Id.*, 14:1-9. Vacuum level controller 119 is

located on the return/waste side of hand piece 118 (i.e., downstream of hand piece

118) and adjusts the level of vacuum throughout Ramey’s entire system. *Id.*, 13:63-

65.

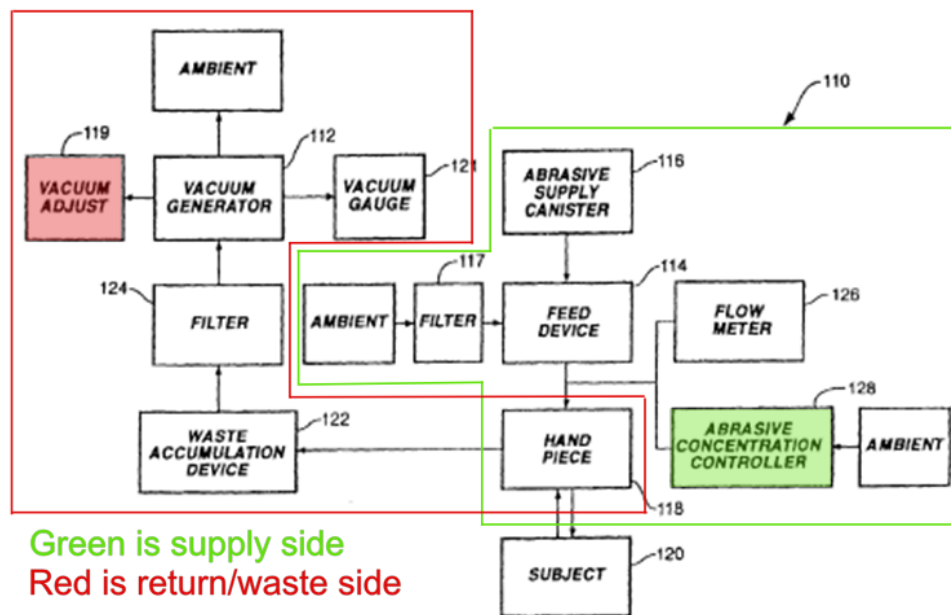


FIG. 8

Ramey, FIG. 9 (annotated)

222. A POSITA would have readily appreciated the benefit of having two

flow rate controllers as providing superior control for users and associated benefits for patients. For example, Ramey explains that it is often desirable to adjust the abrasive concentration controller such that “no abrasive material is being delivered, but that airflow and vacuum pressure remains unchanged.” EUNSUNG-1028, 14:10-24. A system with flow rate controllers both upstream and downstream of the treatment tip would allow an operator to reduce the flow rate of the treatment material to the handpiece to zero utilizing the upstream flow rate controller, while maintaining the ability to adjust the level of suction applied by the handpiece to the treatment area utilizing the downstream flow rate controller.

223. Similarly, a POSITA would have understood that any adjustments to the level of suction in the system downstream from the treatment tip would also adjust the level of suction upstream from the treatment tip and thus the flow rate of the treatment material drawn to the handpiece by the vacuum pump. In some instances, this may not be desired. For example, a low level of suction but a high concentration (i.e., a large flow rate) of treatment material may be desired or vice versa. A system with flow rate controllers both upstream and downstream of the treatment tip would allow an operator to control both the level of suction applied to the treatment area and the flow rate of the treatment material applied to the treatment area through the handpiece. *See* EUNSUNG-1028, 14:10-24.

224. In my opinion, a POSITA would have had a reasonable expectation of

success in combining Waldron's handpiece-mounted flow control valve 52 and vent hole 50 with the Karasiuk-Palmer system given that Waldron also discloses a vacuum-powered microdermabrasion device and operates in a similar manner to the Karasiuk-Palmer system. Ramey further evidences the use of a similar flow rate controller in a microdermabrasion system. EUNSUNG-1028, 14:10-24.

225. It is also my opinion that combining Waldron's handpiece-mounted flow control valve 52 with Karasiuk's device 10 in the manner described above reflects the use of a known method—i.e., Waldron's handpiece-mounted flow control valve 52 and vent hole 50—to obtain predictable results—i.e., a handpiece-mounted flow rate controller for varying the level of suction in a waste line and thus the level of suction applied by the handpiece to a treatment area.

226. This combination would also reflect the use of a known technique—i.e., Waldron's handpiece-mounted flow control valve 52 and vent hole 50—to improve similar devices—i.e., Karasiuk's device 10 and Waldron's treatment tip/wand/tube 22—in the same way—i.e., providing a means for readily adjusting the level of suction in microdermabrasion system through the use of a handpiece-mounted flow rate controller.

227. Moreover, the combination of Waldron with the Karasiuk-Palmer system is merely the application of a known technique (e.g., Waldron's handpiece-mounted flow control valve 52 and vent hole 50) to a known device (e.g.,

Karasiuk's device 10) ready for improvement—i.e., providing a means for readily adjusting the level of suction in Karasiuk-Palmer's waste line, and thus the level of suction applied by the handpiece to a treatment area.

228. In addition to Waldron disclosing that flow control valve 52 is located on a handpiece (i.e., treatment tip/tube/wand 22), in the Karasiuk-Palmer-Waldron combination described above, a POSITA would have found it obvious to locate Waldron's flow control valve 52 on Karasiuk's device 10 for reasons similar to those discussed above in § XI.5.

229. In the Karasiuk-Palmer-Waldron combination described above, a POSITA would have understood Waldron's flow control valve 52 and vent hole 50 as the claimed flow rate controller. This is because Waldron's flow control valve 52 would adjust not only the level of suction applied to the treatment area but would also adjust the level of suction at all components connected upstream from flow control valve 52 and vent hole 50. This includes the level of suction drawn through the container (e.g., Palmer's solution reservoirs 12₁-12₆) selected by Palmer's selector valve means 20 to be in fluid communication with Karasiuk's device 10. As discussed in § XI.4, varying the amount of suction applied to Karasiuk-Palmer's containers would adjust the flow rate of the treatment material from the selected container to Karasiuk's device 10. EUNSUNG-1004, [0059].

230. Thus, in the Karasiuk-Palmer-Waldron combination described above,

a POSITA would have understood Waldron's flow control valve 52 and vent hole 50 as a flow rate controller to adjust a flow rate of the first treatment material (e.g., Palmer's solution 12₁) or the second treatment material (e.g., Palmer's solution 12₂) to the handpiece (e.g., Karasiuk's device 10), wherein the flow rate controller (e.g., Waldron's flow control valve 52 and vent hole 50) is located on the handpiece (e.g., at port 18b on Karasiuk's device 10).

XIII. [GROUND 1C] – Karasiuk, Palmer, and Trueba

1. The Karasiuk-Palmer-Trueba Combination

231. In the Karasiuk-Palmer-Trueba combination, Karasiuk-Palmer's system would have been modified based on Trueba's teachings of computer control and display. For example, in the resulting system, Karasiuk-Palmer's selector means (e.g. Palmer's selector valve 20) would be further controlled by a computer (e.g., Trueba's controller 100), which is controlled by a user input (e.g., Trueba's touch screen 105), to control the flow of treatment solutions from containers (e.g., Palmer's reservoirs 12₁-12₆), so that a user can use the user input device to select a flow of fluids from the containers. The combined device also includes a display (e.g., Trueba's touch screen 105) that indicates which solution is being delivered.

232. A POSITA would have been motivated to modify Karasiuk-Palmer's system by including Trueba's computer control and display for several benefits,

such as added precision (reduced human error), automation, and clarity. For example, by using Trueba's controller to control the order of different treatment materials (and displaying on the touch screen the material being administered), Karasiuk-Palmer-Trueba reduces the chance of applying treatment material in an undesired fashion.

233. As a first example, in the combination, Trueba would allow programming the resulting system to deliver different treatment materials at different times and thus allow automated delivery following complex administration protocols. EUNSUNG-1008, 3:34-38, 4:65-5:17, 6:1-9, 6:27-7:9, 10:52-11:49, FIG. 1.

234. As a second example, Trueba's techniques offer additional benefits in that "[c]omputerized control of medication dosing, which may be programmed by medical personnel for subsequent automated delivery, can help avoid toxic drug interactions, overdoses, and death." EUNSUNG-1008, 6:1-9. For example, Trueba's system can be "programmed to prevent unauthorized alteration of dosages, for example an increase in a dosage of a controlled substance above that authorized by the prescribing physician." EUNSUNG-1008, 12:2-5.

235. As a third example, the combination would further benefit from Trueba's touch screen that shows "a series of images that, when touched with a finger or stylus, program the controller 100" and that "indicate[s] which selections

have been made” and displays “information such as desired dosages, frequency, and potential side effects.” EUNSUNG-1008, 11:42-12:8, FIG. 3.

236. A POSITA would have had a reasonable expectation of success in implementing the combination given the technical similarities between Karasiuk, Palmer, and Trueba. For example, Trueba discloses a system similar to Karasiuk’s, which is “for topical application of a bioactive composition to the surface of the subject, such as a patch of skin.” EUNSUNG-1008, 3:22-27. Trueba also discloses a system similar to Palmer’s, which selects from different treatment materials from different containers. EUNSUNG-1008, 3:4-8, 5:14-26, 11:4-34, FIG. 3.

237. It is my opinion that a POSITA would have been motivated to combine Karasiuk, Palmer and Trueba with a reasonable expectation of success. In the Karasiuk-Palmer-Trueba combination (“Karasiuk-Palmer-Trueba”), the selector means (e.g., Palmer’s selector valve 20) is further controlled by a computer (e.g., Trueba’s controller 100), which is controlled by a user input (e.g., Trueba’s touch screen 105), to control the flow of treatment solutions from containers (e.g., Palmer’s reservoirs 12₁-12₆). The combined device also includes a display (e.g., Trueba’s touch screen 105) that indicates which solution is being delivered.

238. Similar to Karasiuk, Trueba discloses a system “for topical application of a bioactive composition to the surface of the subject, such as a patch of skin.”

EUNSUNG-1008, 3:22-27. Similar to Palmer, Trueba also discloses a system that can select from different treatment materials from different containers.

EUNSUNG-1008, 3:4-8, 5:14-26, 11:4-34, FIG. 3.

239. In addition, Trueba allows programming its system to deliver different treatment materials at different times to allow automated delivery following complex administration protocols. EUNSUNG-1008, 3:34-38, 4:65-5:17, 6:1-9, 6:27-7:9, 10:52-11:49, FIG. 1. In addition to added automation and precision, Trueba's techniques also are beneficial because "[c]omputerized control of medication dosing, which may be programmed by medical personnel for subsequent automated delivery, can help avoid toxic drug interactions, overdoses, and death." EUNSUNG-1008, 6:1-9. For example, Trueba's system can be "programmed to prevent unauthorized alteration of dosages, for example an increase in a dosage of a controlled substance above that authorized by the prescribing physician." EUNSUNG-1008, 12:2-5.

240. In addition, Trueba discloses sequential or simultaneous delivery of treatment fluids from the first container and at least one additional container: "[O]ne or more of the bioactive agents from the reservoirs 54, 56 can be delivered from dispenser 30. The multiple bioactive agents may be administered sequentially or simultaneously." EUNSUNG-1008, 11:21-24.

241. Using Trueba's computer control, multiple compositions can be

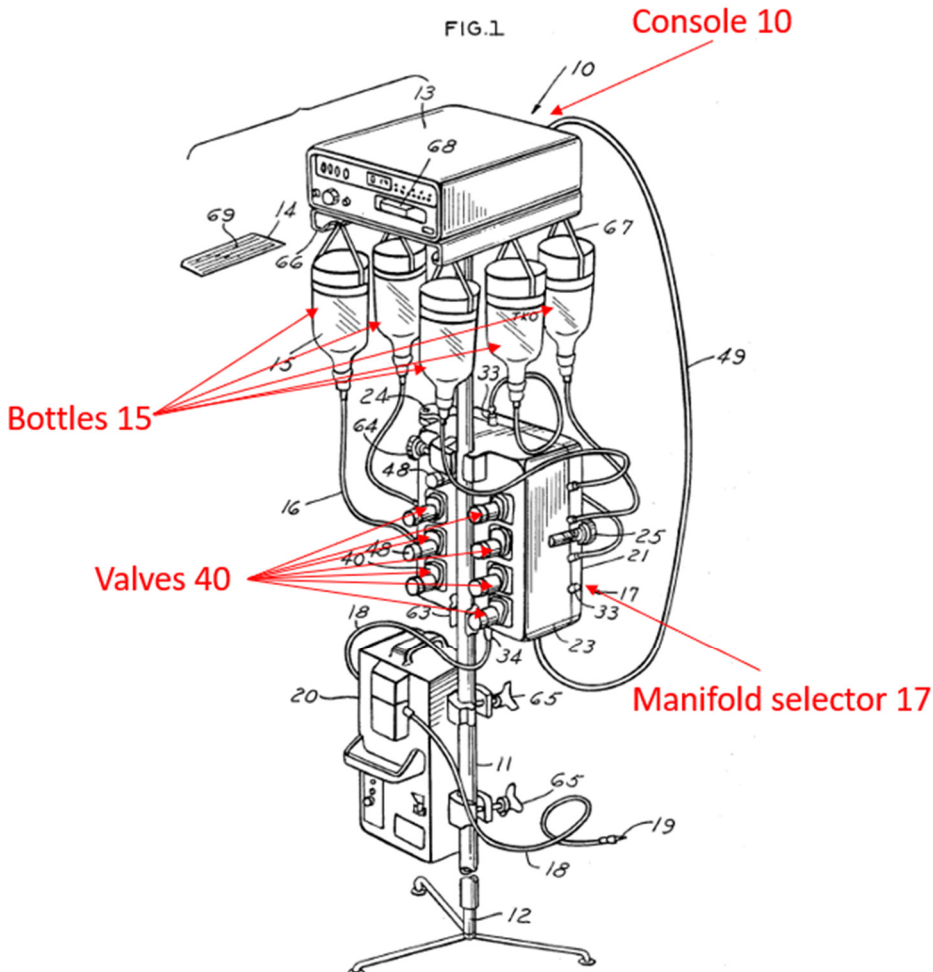
automatically dispensed simultaneously or sequentially. EUNSUNG-1008, 3:4-8, 5:18-6:9, 6:10-16 (“may be used to apply the agent to an area of skin for topical application of a bioactive composition”), 11:4-34 (“Multiple compositions can be dispensed simultaneously or sequentially”). Further, the device can be programmed to respond to changing clinical circumstances. EUNSUNG-1008, 11:15-20 (“For example, only the corticosteroid from reservoir 52 would be administered to a subject having stable reactive airway disease. However, if symptoms persist, then the β -agonist from reservoir 50 also can be delivered.”). Further, the device can be programmed to “prevent unauthorized alteration of dosages” and “permit certain ranges of dosages to be administered.” EUNSUNG-1008, 12:2-9.

242. By the Critical Date, computer (e.g., PLC) controlled fluid delivery systems were well-known. EUNSUNG-1007, FIG. 3; EUNSUNG-1008, FIG. 3; EUNSUNG-1015, Abstract. Compared to manually controlled systems, computer controlled systems provide added precision and automation (e.g., automated delivery of a first treatment for a fixed time followed by a second treatment for a fixed time). EUNSUNG-1008, 11:4-34. Touch screen 105 “may include a series of images that, when touched with a finger or stylus, program the controller 100,” (EUNSUNG-1008, 11:50-59, FIG. 3) and can be used to “indicate which selections have been made” and to display “information such as desired dosages, frequency, and potential side effects.” EUNSUNG-1008, 11:42-49, FIG. 3; EUNSUNG-1014,

Abstract, 1. Further, the touch screen can be operated to select a particular drug or dosage, or to program the controller. EUNSUNG-1008, 11:60-12:8.

243. A POSITA would have been motivated to modify the Karasiuk-Palmer combination by including Trueba's computer control and display to provide added precision (reduce human error), automation, and clarity. A POSITA would have implemented the display and computer control with a reasonable expectation of success because this would constitute the use of a known technique to improve similar devices in the same way. In fact, the modification requires nothing more than automating the manual process in Karasiuk-Palmer with well-known automation techniques. For example, Duchon discloses: "computer 100 controls valve motor 130 through motor driver 132, and monitors position through a Position Monitor feedback signal from potentiometer 134." EUNSUNG-1010, [0098]. As another example, Greenberg discloses: "Switch 30 controls a solenoid that switches the vacuum pump from operatively being connected either to the first or second assembly." EUNSUNG-1006, [0050], FIG. 2. As another example, Armstrong discloses "the rotary selector valve 74 can be provided with a pulse activated solenoid driven stepping mechanism (not shown) such that the activation of a selector switch (not shown) on the handpiece advances the valve in a step-by-step manner to valve the desired fluid on a one step per pulse basis." EUNSUNG-1011, 7:15-20.

244. As another example, Wunsch discloses an apparatus (e.g., console 10) for sequentially dispensing a plurality of solutions through a manifold (e.g., manifold selector 17) that is connected to each of the solutions to be administered. EUNSUNG-1020, Abstract, 7:39-56, 8:17-26, FIGS. 1-4. As shown in FIG. 1, the manifold selector 17 includes a plurality of valves 40, which control the flow of solution from the plurality of bottles 15. EUNSUNG-1020, 6:18-48, 7:16-56. In operation, the user can program the sequencer timer 13 to automatically operate the valves 40 to achieve automatic switching between different solutions and sequential delivery of different solutions. EUNSUNG-1020, 9:36-10:64. The valves 40 can be individually controlled by either reversible electric motors 48 or solenoids 59. EUNSUNG-1020, 6:18-26.



Wunsch, FIG. 1 (annotated)

245. Thus, in the Karasiuk-Palmer-Trueba combination, a POSITA would have been motivated to implement Trueba's computer control in various ways including by controlling Palmer's selector valve 20 using a stepper motor or a solenoid.

246. In the Karasiuk-Palmer-Trueba combination, the selector means (e.g., Palmer's selector valve 20) is further controlled by a computer (e.g., Trueba's controller 100), which is controlled by a user input (e.g., Trueba's touch screen

105), to control the flow of treatment solutions from containers (e.g., Palmer's reservoirs 12₁-12₆). The combined device also includes a display (e.g., Trueba's touch screen 105) that indicates which solution is being delivered.

2. Claims 1, 3-5

247. Karasiuk-Palmer-Trueba renders obvious claim 1 for the same reasons discussed regarding Karasiuk-Palmer. *See supra* § XI.2.

248. In my opinion, Karasiuk-Palmer-Trueba further renders obvious limitation 1.3 based on Trueba's teachings. In particular, to the extent that the term "sequentially" is interpreted to require automatic switching between the delivery of treatment material from the first or second containers, Karasiuk-Palmer-Trueba renders this limitation obvious. EUNSUNG-1008, 3:4-8, 5:18-6:9, 6:10-16, 11:4-34, 12:2-9.

249. It is my opinion that a POSITA would have understood that the term "sequentially" only requires that treatment material from a first container and a second container be delivered one after another, as opposed to "simultaneously," and does not require automatic switching between containers. However, to the extent that this term is interpreted to require automatic switching between containers, this feature is obvious in view of knowledge of the POSITA. For example, Trueba discloses "[c]omputerized control of medication dosing, **which may be programmed by medical personnel for subsequent automated**

delivery, can help avoid toxic drug interactions, overdoses, and deaths.”

EUNSUNG-1008, 6:6-9. If the '607 patent requires the device to be capable of delivering treatment material from two or more containers either sequentially or simultaneously, Trueba allows this functionality: “[O]ne or more of the bioactive agents from the reservoirs 54, 56 can be delivered from dispenser 30. The multiple bioactive agents may be administered sequentially or simultaneously.”

EUNSUNG-1008, 11:21-24. As another example, Wunsch discloses that the user can program the sequencer timer 13 to automatically operate the valves 40 to achieve automatic switching between different solutions and sequential delivery of different solutions. EUNSUNG-1020, 9:36-10:64.

250. To the extent that the term “sequentially” is interpreted to require automatic switching from a first container to a second container, the Karasiuk-Palmer-Trueba combination renders this limitation obvious.

251. Trueba discloses: “Multiple compositions can be dispensed simultaneously or sequentially.” EUNSUNG-1008, 11:4-5. For example, corticosteroid from reservoir 52 would be administered to a subject having stable reactive airway disease, but if symptoms persist, then the β -agonist from reservoir 50 also can be delivered (for example, in response to pressing an activation button or programming the applicator).” EUNSUNG-1008, 11:15-20. Trueba explains “[c]omputerized control of medication dosing, **which may be programmed by**

medical personnel for subsequent automated delivery, can help avoid toxic drug interactions, overdoses, and deaths.” EUNSUNG-1008, 6:6-9.

252. Using Trueba’s computer control, multiple compositions can be automatically dispensed simultaneously or sequentially. EUNSUNG-1008, 3:4-8, 5:18-6:9 (“Several modules may contain the same or different bioactive compositions”), 6:10-16 (“may be used to apply the agent to an area of skin for topical application of a bioactive composition”), 11:4-34 (“Multiple compositions can be dispensed simultaneously or sequentially”). Further, the device can be programmed to respond to changing clinical circumstances. EUNSUNG-1008, 11:15-20 (“For example, only the corticosteroid from reservoir 52 would be administered to a subject having stable reactive airway disease. However, if symptoms persist, then the β -agonist from reservoir 50 also can be delivered.”). Further, the device can be programmed to “prevent unauthorized alteration of dosages” and “permit certain ranges of dosages to be administered.” EUNSUNG-1008, 12:2-9.

253. As discussed above in § XIII.1, Karasiuk-Palmer-Trueba’s system employs “[c]omputerized control of medication dosing, which may be programmed by medical personnel for subsequent automated delivery,” as taught by Trueba. EUNSUNG-1008, 6:6-9. A POSITA would have found it obvious to employ Trueba’s automation in the system of Karasiuk-Palmer provide added

precision (avoiding human error), automation, and clarity, resulting in automatic switching and delivery of treatment material in a sequential manner.

254. As discussed above in § XIII.1, in the Karasiuk-Palmer-Trueba combination, Trueba's controller 100 is configured to control the delivery of treatment material to provide added precision, automation, and clarity. Thus, the Karasiuk-Palmer-Trueba combination renders this limitation obvious. Similarly, dependent claims 2-10 that inherit the same subject matter are rendered obvious by Karasiuk-Palmer-Trueba.

3. Claim 2

[2.pre] The system of claim 1, further comprising:

[2.1] a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece, wherein the flow rate controller is located on the handpiece or on the console; and

255. For the reasons discussed above with respect to claim 3, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

256. For the reasons discussed above with respect to claim 4, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious locating the flow rate controller on the handpiece.

257. For the reasons discussed above with respect to claim 5, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious locating the flow

rate controller on the console.

[2.2] a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

258. As I will discuss below with respect to claim 7, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious a user input device to select the first treatment material or the second treatment material for delivery to the handpiece based on Trueba's teachings.

4. Claim 6

[6] The system of claim 1, further comprising a computing device configured to control at least one function of the system.

259. It is my opinion that the Karasiuk-Palmer-Trueba combination renders obvious a computing device (e.g., Trueba's controller 100) configured to control at least one function of the system (e.g., delivery of treatment material). As discussed in § XIII.1, the Karasiuk-Palmer-Trueba combination includes a computing device (e.g., Trueba's controller 100) configured to control at least one function (e.g., delivery of treatment material) of the system. EUNSUNG-1008, 3:34-38, 4:65-5:17, 6:1-9, 6:27-7:9, 10:52-11:49, 12:2-5, FIG. 1.

5. Claim 7

[8] The system of claim 1, further comprising a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

260. Karasiuk-Palmer-Trueba renders obvious claim 7 for the same reasons discussed regarding Karasiuk-Palmer. *See supra* § XI.7. I believe that Karasiuk-

Palmer-Trueba further renders obvious claim 7 based on Trueba's teachings.

261. It is my opinion that Karasiuk-Palmer-Trueba combination renders obvious a user input device (e.g., Trueba's touch screen 105) to select the first treatment material (e.g., Palmer's solution 34₁) or second treatment material (e.g., Palmer's solution 34₂) for delivery to the handpiece (e.g., Karasiuk's device 10). As discussed above in § XIII.1, the Karasiuk-Palmer-Trueba combination includes a user input device (e.g., Trueba's touch screen 105) to select the first treatment material or the second treatment material for delivery to the handpiece.

6. Claim 8

[8] The system of claim 7, wherein the user input device comprises a touch screen.

262. It is my opinion that Karasiuk-Palmer-Trueba renders obvious that the user input device (e.g., Trueba's touch screen 105) comprises a touch screen. As discussed above in § XIII.1, in the Karasiuk-Palmer-Trueba combination, the system comprises a touch screen (e.g., Trueba's touch screen 105) to select the first treatment material or the second treatment material for delivery to the handpiece.

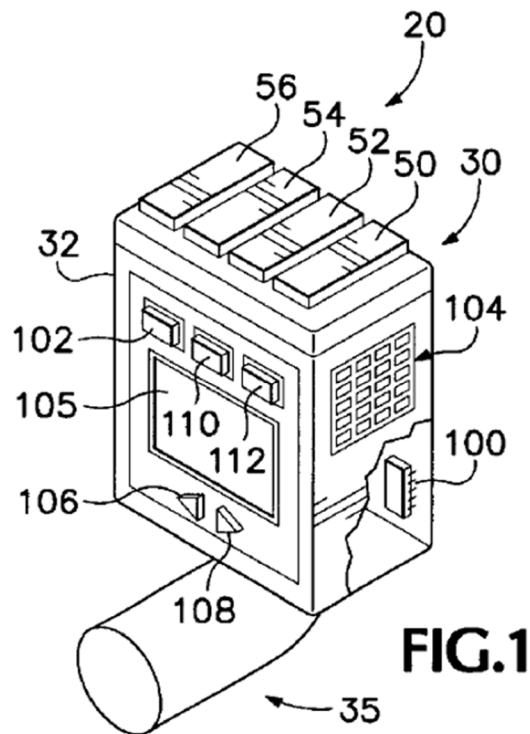
7. Claim 9

[9] The system of claim 7, wherein the user input device is positioned on the console.

263. Karasiuk-Palmer-Trueba renders obvious claim 9 for the same reasons discussed regarding Karasiuk-Palmer. *See supra* § XI.8. I believe that Karasiuk-Palmer-Trueba further renders obvious claim 9 based on Trueba's teachings.

264. It is my opinion that the Karasiuk-Palmer-Trueba combination renders obvious positioning a user input device (e.g., Trueba's touch screen 105) on a console (e.g., Palmer's mobile cart 170).

265. Trueba's exemplary embodiment is a handheld pulmonary inhaler, in which containers 50-56, ejection heads 40-46, controller 100, and touch screen 105 are contained within body 32 of applicator 30. EUNSUNG-1008, 10:52-12:8; FIG. 1.



Trueba, FIG. 1

266. But Trueba also suggests alternative embodiments “for topical application of a bioactive composition to the surface of the subject, such as a patch

of skin, rather than delivering the composition to a mucous membrane via a body orifice.” EUNSUNG-1008, 3:22-27. A POSITA would have recognized that for such an alternative use, e.g., delivering treatment material to a skin surface, a larger volume of or different, heavier treatment material may be required. A POSITA would have further recognized that locating Trueba’s containers 50-56, ejection heads 40-46, controller 100, and touch screen 105 within body 32 of applicator 30 may cause the applicator to become too large and unwieldy to handle when used with a larger volume or heavier treatment material than that used in the disclosed pulmonary inhaler embodiment.

267. Therefore, for use in different embodiments, a POSITA would have recognized that it would be advantageous to place Trueba’s containers 50-56, ejection heads 40-46, controller 100, and touch screen 105 in a separate location from the body 32 of applicator 30, such as in a console. In the Karasiuk-Palmer-Trueba combination, a POSITA would have found it obvious to position Trueba’s touch screen 105 on Palmer’s mobile cart 170 for several reasons.

268. **First**, positioning a user input device like Trueba’s touch screen 105 on a console was well-known and would have been within a POSITA’s general knowledge. For example, Duchon discloses a system for injecting radiographic contrast material into a blood stream that includes a console 12 with a user interface 55 (e.g., control switches 56 and display 58) for controlling the system



270. **Second**, it my opinion that a POSITA would have been motivated to position interconnected devices with each other to reduce manufacturing complexity and cost. As discussed in § XIII.1, Trueba’s touch screen 105

interfaces with controller 100 to control the operation of Palmer's selector valve means 20, which is located on Palmer's mobile cart 170 in control unit enclosure

35. EUNSUNG-1005, 9:58-10:16, FIG. 11B. A POSITA would have found it obvious to position those devices in the same location, i.e., on Palmer's mobile cart 170.

271. **Third**, I believe that positioning Trueba's touch screen 105 on Palmer's mobile cart 170 would have been obvious to try. A POSITA would have recognized a finite number of identified, predictable locations to locate Trueba's touch screen 105 in the Karasiuk-Trueba-Palmer system: either on Karasiuk's device 10 or on Palmer's mobile cart 170 (e.g., on control unit enclosure 35). Given these options, I believe that it would have been obvious to a POSITA to try locating Trueba's touch screen 105 on Palmer's mobile cart 170.

272. **Fourth**, I believe that positioning Trueba's touch screen 105 on Palmer's mobile cart 170 would have been an obvious design choice. In my opinion, choosing to locate Trueba's touch screen 105 on Palmer's mobile cart 170 would not result in any difference in the function of the Karasiuk-Palmer-Trueba system and the resulting device would function as a POSITA would have expected.

273. Thus, the combined teachings of Karasiuk, Palmer, and Trueba render obvious positioning the user input device (e.g., Trueba's touch screen 105) on the console (e.g., Palmer's mobile cart 170).

8. Claim 10

[10] The system of claim 1, wherein the console comprises a display.

274. It is my opinion that the Karasiuk-Palmer-Trueba combination renders obvious that the console comprises a display (e.g., Trueba's touch screen 105). For the reasons discussed above with respect to claim 9, in the Karasiuk-Palmer-Trueba combination, I believe that a POSITA would have found it obvious to position a display (e.g., Trueba's touch screen 105) on the console (e.g., Palmer's mobile cart 170).

9. Claim 11

275. Claim 11 claims similar subject matter recited in claims 1 and 6.

[11.pre] A skin treatment system, comprising:

276. For similar reasons discussed above with respect to limitation 1.pre, I believe that the combined teachings of Karasiuk, Palmer, and Trueba render obvious a skin treatment system.

[11.1] a console configured to receive a first container containing a first treatment material and a second container containing a second treatment material;

277. For similar reasons discussed above with respect to limitation 1.1, I believe that the combined teachings of Karasiuk, Palmer, and Trueba render obvious a console configured to receive a first container containing a first treatment material and a second container containing a second treatment material.

[11.2] a handpiece configured to couple to a tip that can be placed against skin to perform skin treatment;

278. Claim 1's limitation 2 recites "a handpiece configured to couple to a tip that can be ***pressed*** against skin to perform skin treatment." In my opinion, a POSITA would not appreciate any difference between "pressed" and "placed" as it relates to the patentability of the '607 claims over the prior art discussed herein.

279. Thus, for similar reasons discussed above with respect to limitation 1.2, I believe that the combined teachings of Karasiuk, Palmer, and Trueba render obvious a handpiece configured to couple to a tip that can be placed against skin to perform skin treatment.

[11.3] a supply line extending between the handpiece and the console for sequentially delivering treatment material to the handpiece from the first container or the second container;

280. Claim 1's limitation 3 recites "a supply line ***connected between*** the handpiece and the console for sequentially delivering treatment material to the handpiece from the first container or the second container." In my opinion, a POSITA would not appreciate any difference between "connected between" and "extending between" as it relates to the patentability of the '607 claims over the prior art discussed herein.

281. Thus, for similar reasons discussed above with respect to limitation 1.3, I believe that the combined teachings of Karasiuk, Palmer, and Trueba render obvious a supply line extending between the handpiece and the console for

sequentially delivering treatment material to the handpiece from the first container or the second container.

[11.4] a waste line extending between the handpiece and the console;

282. Claim 1's limitation 4 recites "a waste line ***connected between*** the handpiece and the console." In my opinion, a POSITA would not appreciate any difference between "connected between" and "extending between" as it relates to the patentability of the '607 claims over the prior art discussed herein.

283. Thus, for similar reasons discussed above with respect to limitation 1.4, I believe that the combined teachings of Karasiuk, Palmer, and Trueba render obvious a waste line extending between the handpiece and the console.

[11.5] a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is placed against skin; and

284. Claim 1's limitation 5 recites "a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is ***pressed*** against skin." In my opinion, a POSITA would not appreciate any difference between "pressed" and "placed" as it relates to the patentability of the '607 claims over the prior art discussed herein.

285. Thus, for similar reasons discussed above with respect to limitation

1.5, I believe that the combined teachings of Karasiuk, Palmer, and Trueba render obvious a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is placed against skin.

[11.6] a computing device configured to control at least one function of the system.

286. For the reasons discussed above with respect to claim 6, I believe the combined teachings of Karasiuk, Palmer, and Trueba render obvious a computing device configured to control at least one function of the system.

10. Claim 12

[12] The system of claim 11, further comprising: a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece, wherein the flow rate controller is located on the handpiece or on the console; and a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

287. Claim 12 claims similar subject matter recited in claim 2, which in turn claims similar subject matter recited in claims 3-5 and 7.

288. For similar reasons discussed above with respect to claim 3, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

289. For similar reasons discussed above with respect to claim 4, I believe

that the combination of Karasiuk, Palmer, and Trueba renders obvious locating the flow rate controller on the handpiece.

290. For similar reasons discussed above with respect to claim 5, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious locating the flow rate controller on the console.

291. For similar reasons discussed above with respect to claim 7, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

11. Claim 13

[13] The system of claim 11, further comprising a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

292. Claim 13 claims similar subject matter recited in claim 3. For similar reasons discussed with respect to claim 3, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

12. Claim 14

[14] The system of claim 13, wherein the flow rate controller is located on the handpiece.

293. Claim 14 claims similar subject matter recited in claim 4. For similar

reasons discussed with respect to claim 4, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious the flow rate controller being located on the handpiece.

13. Claim 15

[15] The system of claim 13, wherein the flow rate controller is located on the console.

294. Claim 15 claims similar subject matter recited in claim 5. For similar reasons discussed with respect to claim 5, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious the flow rate controller being located on the console.

14. Claim 16

[16] The system of claim 11, further comprising a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

295. Claim 16 claims similar subject matter recited in claim 7. For similar reasons discussed with respect to claim 7, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

15. Claim 17

[17] The system of claim 16, wherein the user input device comprises a touch screen.

296. Claim 17 claims similar subject matter recited in claim 8. For similar reasons discussed with respect to claim 8, I believe that the combination of

Karasiuk, Palmer, and Trueba renders obvious the user input device comprising a touch screen.

16. Claim 18

[18] The system of claim 16, wherein the user input device is positioned on the console.

297. Claim 18 claims similar subject matter recited in claim 9. For similar reasons discussed with respect to claim 9, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious the user input device being positioned on the console.

17. Claim 19

[19] The system of claim 11, wherein the console comprises a display.

298. Claim 19 claims similar subject matter recited in claim 10. For similar reasons discussed with respect to claim 10, I believe that the combination of Karasiuk, Palmer, and Trueba renders obvious the console comprising a display.

18. Claim 20

299. Claim 20 claims similar subject matter recited in claim 1 and claim 2, which in turn claims similar subject matter recited in claims 3-5 and 7.

[20.pre] A skin treatment system, comprising:

300. For similar reasons discussed above with respect to limitation 1.pre, I believe that the combination of Karasiuk and Palmer renders obvious a skin treatment system.

[20.1] a console configured to receive a first container containing a first treatment material and a second container containing a second treatment material;

301. For similar reasons discussed above with respect to limitation 1.1, I believe that the combination of Karasiuk and Palmer renders a console configured to receive a first container containing a first treatment material and a second container containing a second treatment material.

[20.2] a handpiece configured to couple to a tip that can be pressed against skin to perform skin treatment;

302. For similar reasons discussed above with respect to limitation 1.2, I believe that the combination of Karasiuk and Palmer renders obvious a handpiece configured to couple to a tip that can be pressed against skin to perform skin treatment.

[20.3] a supply line connected between the handpiece and the console for sequentially delivering treatment material to the handpiece from the first container or the second container;

303. For similar reasons discussed above with respect to limitation 1.3, I believe that the combination of Karasiuk and Palmer renders obvious a supply line connected between the handpiece and the console for sequentially delivering treatment material to the handpiece from the first container or the second container.

[20.4] a waste line connected between the handpiece and the console;

304. For similar reasons discussed above with respect to limitation 1.4, I believe that the combination of Karasiuk and Palmer renders obvious a waste line

connected between the handpiece and the console.

[20.5] a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is pressed against skin;

305. For similar reasons discussed above with respect to limitation 1.5, I believe that the combination of Karasiuk and Palmer renders obvious a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is pressed against skin.

[20.6] a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece, wherein the flow rate controller is located on the handpiece or on the console; and

306. For similar reasons discussed above with respect to claim 3, I believe that the combination of Karasiuk and Palmer renders obvious a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

307. For similar reasons discussed above with respect to claim 4, I believe that the combination of Karasiuk and Palmer renders obvious locating the flow rate controller on the handpiece.

308. For similar reasons discussed above with respect to claim 5, I believe that the combination of Karasiuk and Palmer renders obvious locating the flow rate

controller on the console.

[20.7] a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

309. For similar reasons discussed above with respect to claim 7, I believe that the combination of Karasiuk and Palmer renders obvious a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

XIV. [GROUND 1D] – Karasiuk, Palmer, Trueba, and Waldron

1. Claims 2, 4, 12, 14, 20

310. It is my opinion that the combination of Karasiuk, Palmer, Trueba, and Waldron render obvious claims 2, 4, 12, 14, and 20 for the same reasons discussed regarding Karasiuk-Palmer-Trueba. I believe that the combination of Karasiuk, Palmer, Trueba, and Waldron further renders obvious claims 2, 4, 12, 14, and 20 based on Waldron’s teachings for similar reasons explained above with respect to Karasiuk and Waldron.

XV. [GROUND 2A] – Greenberg

1. Claim 1

[1.pre] A skin treatment system, comprising:

311. It is my opinion that Greenberg renders obvious a system for treating skin. Greenberg, titled “Apparatus for Variable Micro Abrasion of Human Tissue and/or Hides Using Different Particle Size and Types of Abrasive Particles,”

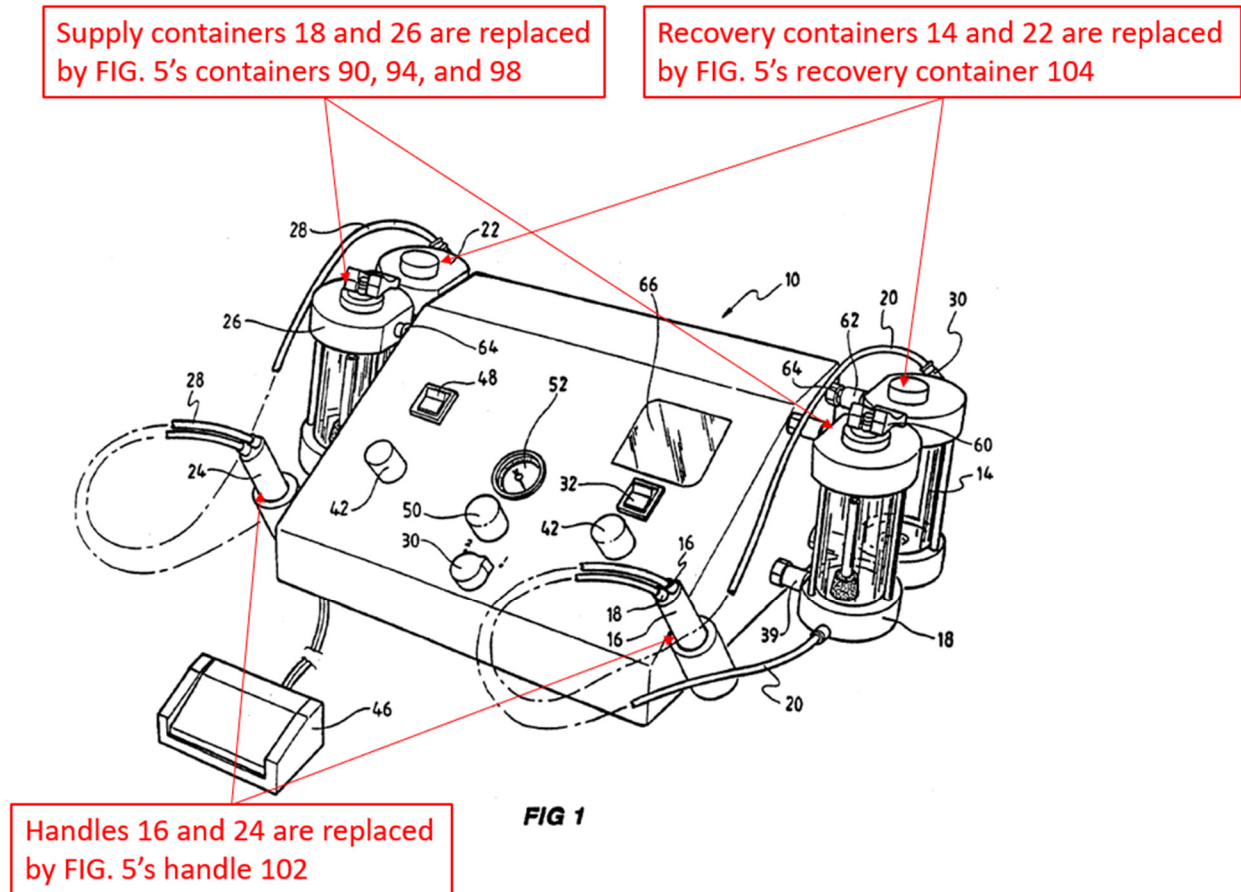
discloses “a microdermabrasion apparatus for providing treatment of skin or other surfaces.” EUNSUNG-1006, Cover, [0003]-[0012], FIGS. 1, 3.

[1.1] a console configured to receive a first container containing a first treatment material and a second container containing a second treatment material;

312. It is my opinion that Greenberg renders obvious a console (e.g., apparatus 10) configured to receive a first container (e.g., container 90) containing a first treatment material (e.g., standard aluminium oxide particles 92) and a second container (e.g., container 94) containing a second treatment material (e.g., organically coated aluminium oxide particles 96).

313. As shown in FIG. 1, Greenberg discloses “an **apparatus 10** for making abrasions including a vacuum pump 12 operatively connected in series to either a first assembly including a **recovery container 14**, a **handle 16** and a **supply container 18** by tubes 20, or operatively connected to a second assembly including a recovery container 22, a handle 24 and a supply container 26 by tubes 28.” EUNSUNG-1006, [0049], FIG. 1. As shown in FIG. 1, Greenberg’s apparatus 10 is designed to receive and connect the containers and the handle, and enclose various components within the apparatus, allowing the user to control fluid flow via switches (e.g., switch 30). EUNSUNG-1006, [0049]-[0064]. Thus, a POSITA would have recognized that Greenberg’s apparatus corresponds to a console that receives multiple containers. This aligns with the disclosure of console 12 in the ’607 patent, which receives/connects multiple containers (EUNSUNG-

1001, 14:38-48), a valve system (EUNSUNG-1001, 9:18-20, 18:38-42), a handpiece (EUNSUNG-1001, 18:46-55), a vacuum pump (EUNSUNG-1001, 11:5-6, 18:38-45), a filter 28 (EUNSUNG-1001, 6: 6-8), and a waste container (EUNSUNG-1001, 7:47-48, FIG. 1).



Greenberg, FIG. 1 (annotated)

314. To the extent Patent Owner argues that Greenberg's apparatus does not include a console, a POSITA would have been motivated and found it obvious to place Greenberg's apparatus in a console for increased portability and/or organization. EUNSUNG-1005, 9:58-10:2, FIGS. 11A-11C. Using a console to

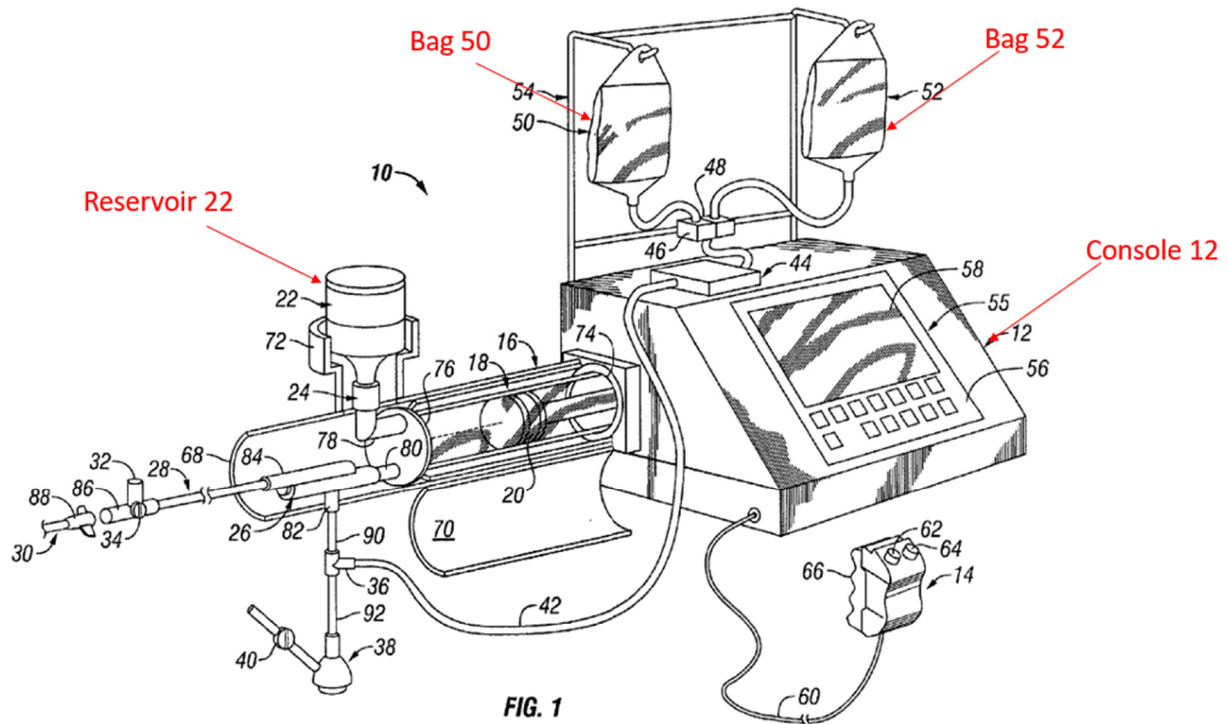
house similar medical devices were well-known and would have been within a POSITA's general knowledge. EUNSUNG-1010, FIGS. 2A-2G, 7A-7D, [0063] ("Console 12 houses the electrical controls for system 10, together with the motors which drive piston 20 and peristaltic pump 44."), [0088], [0154] ("The console and power supply are mounted to a cart, generally indicated at 402 which includes wheels for easy movement and which is preferably designed to provide stability and deter tipping when used in its intended method"); EUNSUNG-1005, 9:58-10:2, FIGS. 11A-11C; EUNSUNG-1011, FIG. 2, 4:57-60, 5:55-61. Indeed, a POSITA would have viewed a console as one of a finite number of options to achieve increased portability and/or organization that would have been obvious to try. *Id.* A POSITA would have had a reasonable expectation of success to place Greenberg's apparatus in a console, as it would constitute the use of a known technique to improve similar devices in the same way. *Id.*

315. For example, Duchon discloses a medical fluid delivery system where the user can choose the desired fluid (e.g., contrast material or saline) from multiple fluid containers (e.g., reservoir 22 or bag 50). EUNSUNG-1010, Abstract, FIG. 1, [0006]. Duchon discloses in relevant part:

[0063] **Console 12** houses the electrical controls for system 10, together with the motors which drive piston 20 and peristaltic pump 44. On the front surface of **console 12**, user interface 55 provides control switches 56 and display 58 through which the user may enter control settings and monitor the operational state

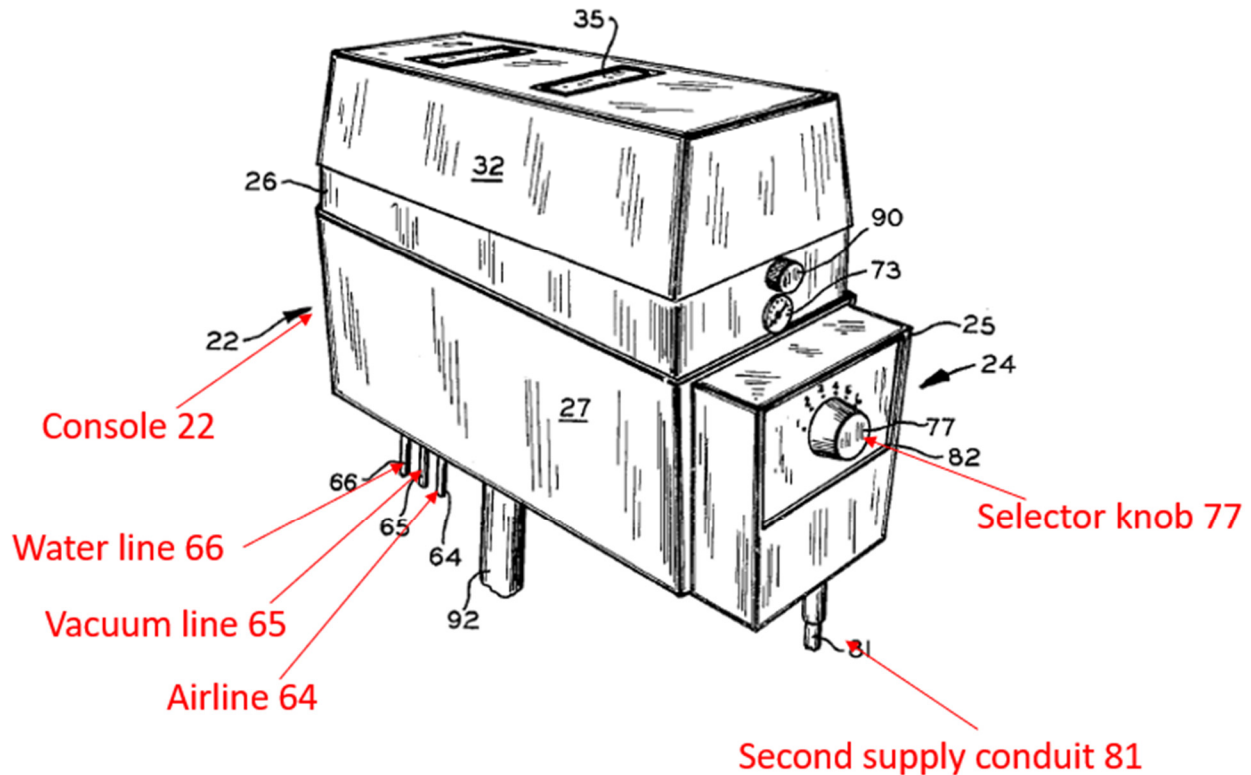
of system 10. The console can be free-standing, preferably configured for mounting on a transport cart assembly.

EUNSUNG-1010, [0063].



Duchon, FIG. 1 (annotated)

316. As another example, Armstrong discloses a medical fluid delivery system where the user can choose a desired fluid from several fluid containers (e.g., reservoirs 46). EUNSUNG-1011, Abstract, FIG. 1, FIG. 2.



Armstrong, FIG. 2 (annotated)

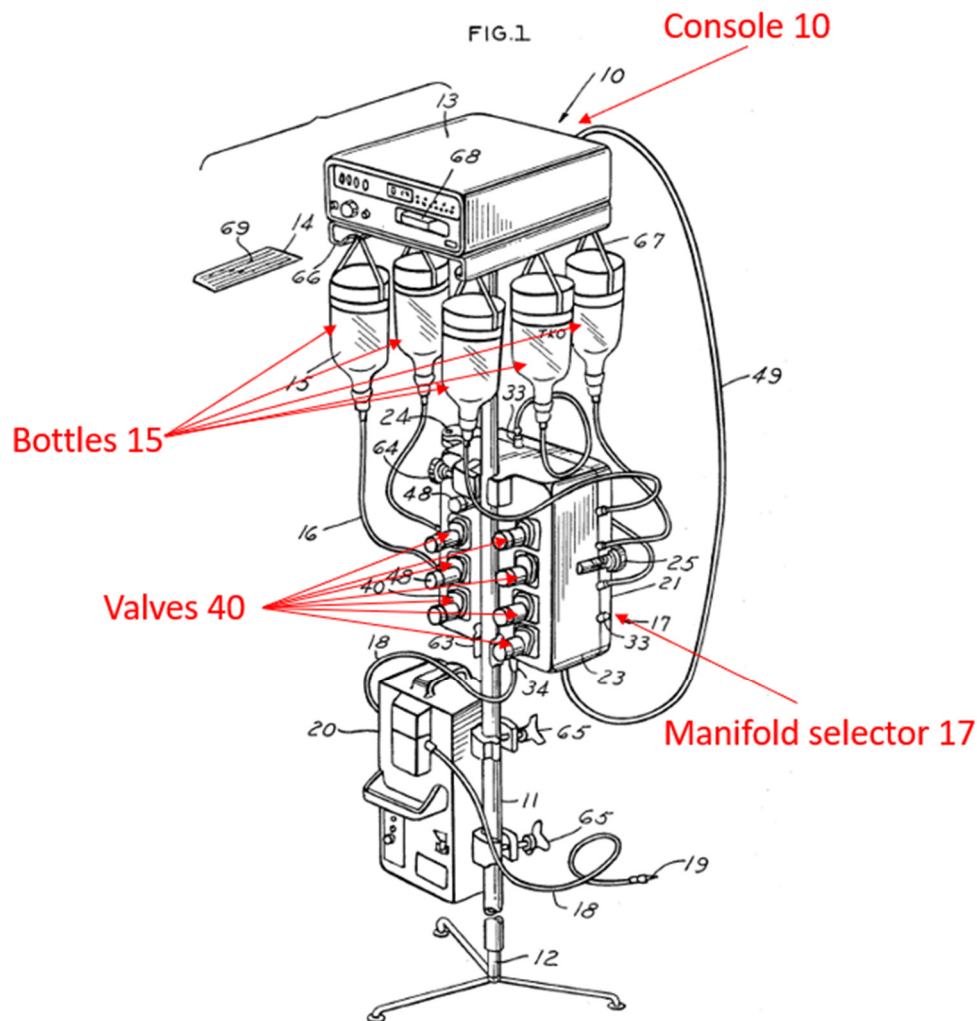
317. Armstrong discloses in relevant part:

FIG. 2 shows the system 21 of FIG. 1 with the control box 82 secured to the supply station 22. In this embodiment the supply station 22 is supported by a pedestal 92 so that, if desired, the entire system 21 may be placed next to the patient treatment area. This embodiment is typically used in a dental care center as opposed to a surgical theater usage.

EUNSUNG-1011, 5:55-61.

318. As another example, Wunsch discloses an apparatus (e.g., console 10) for sequentially dispensing a plurality of solutions through a manifold that is connected to each of the solutions to be administered. EUNSUNG-1020, Abstract, 7:39-56, 8:17-26, FIGS. 1-4. As shown in FIG. 1, the manifold selector 17 includes

a plurality of valves 40, which control the flow of solution from the plurality of bottles 15. EUNSUNG-1020, 6:18-48, 7:16-56. In operation, the user can program the sequencer timer 13 to automatically operate the valves 40 to achieve automatic switching between different solutions and sequential delivery of different solutions. EUNSUNG-1020, 9:36-10:64.



EUNSUNG-1020, FIG. 1 (annotated)

319. As discussed in § X.5 above, Greenberg describes providing at least three different supply containers in the apparatus 10. A POSITA would have

understood two of these three containers correspond to the first container and the second container received at the console. EUNSUNG-1006, [0077], modified FIG.

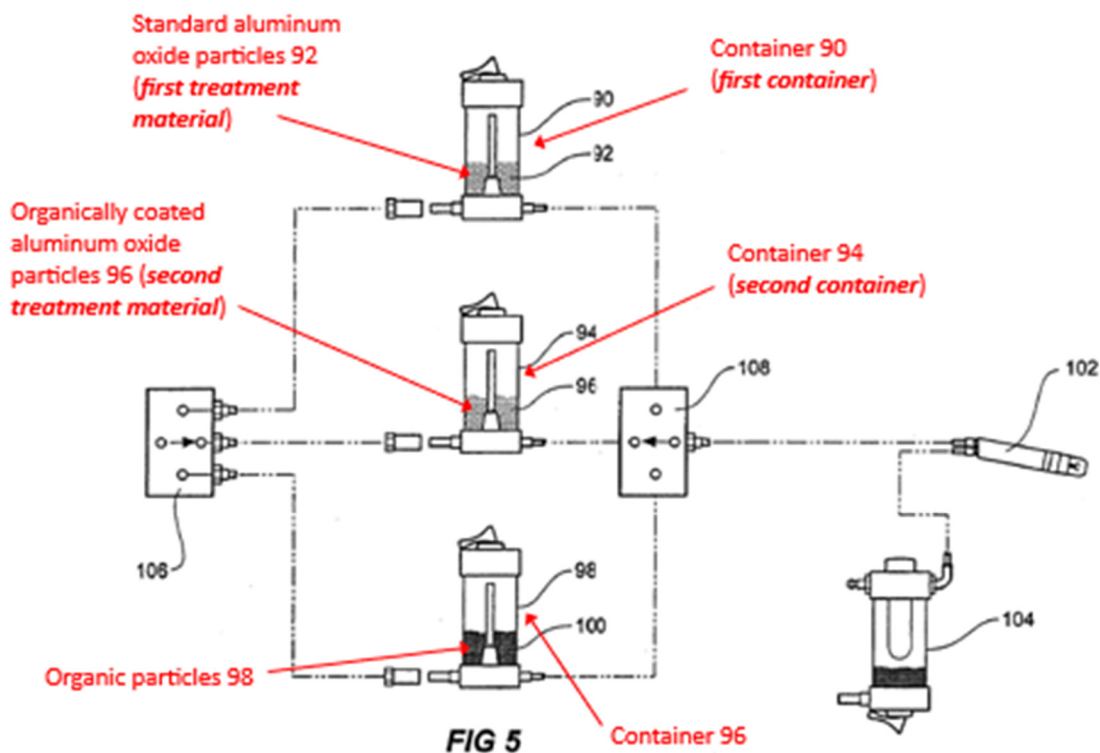
1 (as modified by FIG. 5). Specifically, Greenberg discloses:

[0077] This can be achieved in the present apparatus by having an apparatus with a plurality of supply containers housing different particles. As shown in FIG. 5 for example, there may be three different supply containers. Container 90 may house standard aluminium oxide particles 92, supply container 94 may house organically coated aluminium oxide particles 96 whilst supply container 98 may house organic particles 100. 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 than connects that supply container to the handle 102 and recovery container 104.

EUNSUNG-1006, [0077].

320. Further, as shown in FIG. 5, Greenberg's three supply containers contain "different particles each of which performs different types of treatment such as abrasion." EUNSUNG-1006, Abstract, [0077]. Specifically, Greenberg discloses: "Preferably at least one said supply container includes organic type particles" (EUNSUNG-1006, [0023]) and "[t]he organic particles may not only contain essential oils but they may also contain fragrances that on impact with the skin impart some of those properties." EUNSUNG-1006, [0082]. Greenberg also discloses that "other additions to the synthetic or organic materials may be used... such as tea tree oils and essences, colourings and so on." EUNSUNG-1006, [0087], [0011]-[0012]. Greenberg discloses an example where the system can

choose from three different treatment materials, including (1) purely organic materials, (b) a mixture of abrasive particles such as aluminum oxide mixed with organic materials, and (c) abrasive particles that are coated with organic materials. EUNSUNG-1006, [0072]-[0077].



Greenberg, FIG. 5 (annotated)

321. For example, “[c]ontainer 90 may house standard aluminum oxide particles 92, supply container 94 may house organically coated aluminum oxide particles 96 whist supply container 98 may house organic particles 100.”

EUNSUNG-1006, [0077]. Two of these different treatment materials would have been understood as a first treatment material (e.g., standard aluminum oxide particles 92) and a second treatment material (e.g., organically coated aluminum oxide particles 96).

322. Thus, Greenberg renders obvious a console (e.g., apparatus 10) configured to receive a first container (e.g., container 90) containing a first treatment material (e.g., standard aluminium oxide particles 92) and a second container (e.g., container 94) containing a second treatment material (e.g., organically coated aluminium oxide particles 96).

[1.2] a handpiece configured to couple to a tip that can be pressed against skin to perform skin treatment;

323. It is my opinion that Greenberg renders obvious a handpiece (e.g., handle 16/102) configured to couple to a tip (e.g., end of handle 16/102 with aperture 40) that can be pressed against skin to perform skin treatment (e.g., microdermabrasion).

324. Greenberg describes a handpiece (e.g., “handle 16” (FIG. 1) and “handle 102” (FIG. 5)) that includes a tip, the end of handle 102 with aperture 40, which is pressed against skin to perform microdermabrasion. Specifically, Greenberg discloses in relevant part:

In operation, the vacuum pump draws air through either one of the assemblies and the corresponding recovery container and handle. **The handle includes an aperture 40, which is**

positioned against the surface to be treated, and which then causes air and thus particles to be drawn from the corresponding [supply] container. The stream of particles then impinges on the surface against which the aperture is positioned causing micro-abrasions and is subsequently drawn into the recovery container together with any abraded surface debris.

EUNSUNG-1006, [0052].

325. I note that paragraph 52 of Greenberg reads, in relevant part, “particles to be drawn from the corresponding *recovery* container.” EUNSUNG-1006, [0052]. In my opinion, the emphasized portion is an erratum and should read “supply.” A POSITA would recognize that used particles and abraded debris from the recovery container would not be applied to the treatment site. Rather, as is clear from the subsequent paragraph, the particles are drawn from the *supply* container when the tip is pressed against the skin:

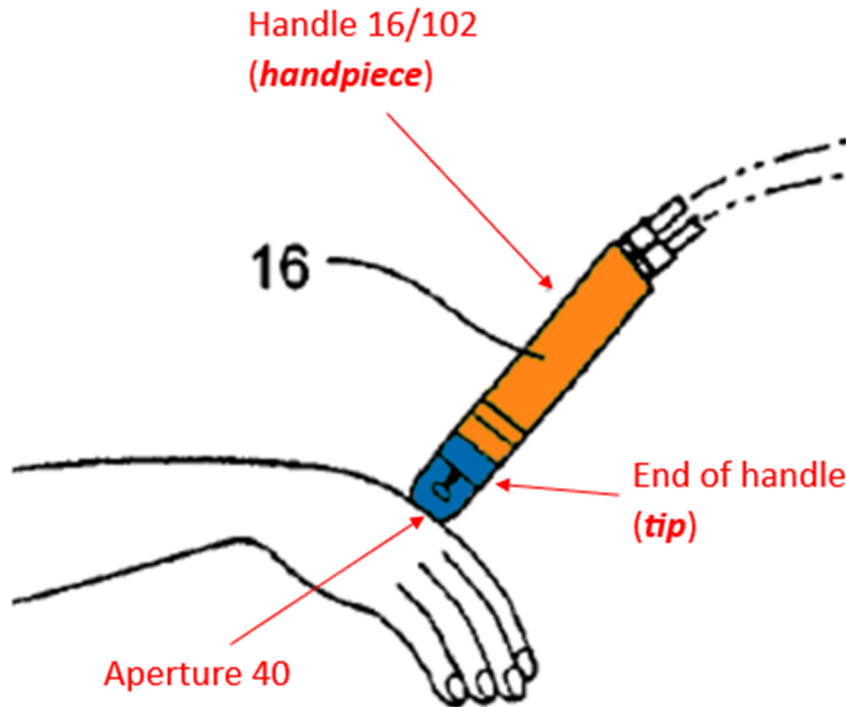
When a low-level of micro-abrasion is required the switch 30 is operated so that the solenoid operatively connects the vacuum pump in series with the first assembly that in this example houses lighter abrasive particles. In such a configuration the vacuum pump provides suction through the recovery container 14, handle 16 and supply container 18. The supply container 18 includes an inlet 39 connected to a regulator 42 having an inlet 44 the regulator controlling the amount of air entering the supply container. **The air entering the supply container aerates the particles, with the magnitude of air flow providing control over the flux or density of particles drawn though the apparatus.**

EUNSUNG-1006, [0053].

326. A POSITA would have understood Greenberg’s handle 16/102

(depicted below in orange) and the end of the handle 102 with aperture 40

(depicted below in blue) as teaching the claimed handpiece and tip, respectively.



Greenberg, FIG. 3 (excerpt and annotated)

327. Greenberg does not describe the connection between the body of handle 16/102 and the tip—i.e., the end of the handle with aperture 40, but it appears to be permanently affixed to handle 16/102. In this way, I believe that Greenberg renders obvious a tip coupled to a handpiece. This aligns with the disclosure of the '607 patent, which discloses:

The tip 34 can be *permanently* or temporarily coupled to the distal end 36 of the main body 30. In some embodiments, the tip 34 is disposable. As used herein, the term “disposable,” when applied to a system or component (or combination of

components), such as a tip, container, or pad, is a broad term and means, without limitation, that the component in question is used a finite number of times and then discarded. Some disposable components are used only once and then discarded. Other disposable components are used more than once and then discarded. In some embodiments, the tip 34 is removably coupled to the main body 30 such that the tip may be removed from the main body 30 and thrown away to avoid cross-contamination. In other embodiments, the tip 34 is a reusable tip that can be cleaned, for example by autoclaving, after each use. The tip 34 can thus be used for any number of procedures as desired.

EUNSUNG-1001, 7:12-27.

328. Thus, Greenberg renders obvious a handpiece (e.g., handle 16/102) configured to couple (e.g., permanently) to a tip (e.g., end of handle 16/102 with aperture 40) that can be pressed against skin to perform skin treatment (e.g., microdermabrasion).

329. I have also been asked to consider whether it would have been obvious to a POSITA to modify Greenberg such that the tip is removable (i.e., temporarily coupled). I believe that it would have been within the general knowledge of a POSITA to modify Greenberg's handle 16/102 to include a detachable tip and a POSITA would have been motivated to do so.

330. A POSITA would have recognized that Greenberg's tip (i.e., the end of handle 16/102 with aperture 40), which is placed against a patient's skin and comes into contact with abraded debris from the skin surface, would need to be either sterilized or replaced between patients. *See, e.g.*, EUNSUNG-1030, 1 ("In

our sample microdermabrasion, there was visible evidence that blood and particles of skin were deposited on the inner surface of the cap of the hand piece It is not necessary to see gross blood on the hand piece to realize that infectious particles could lodge there after patient contact.”).

331. Detachable tips were well known in the art. *See e.g.*, EUNSUNG-1004, [0015], [0042], [0047], [0050], [0063], Claim 3, FIG. 1; EUNSUNG-1033, 4:66-5:40, FIGS. 8-9; EUNSUNG-1028, 17:11-32, 49-60, FIG. 12A. Waldron, for example, recognizes that a microdermabrasion treatment tip may be “steam or chemical sterilized between uses” or include “a suitable removable and replaceable tip.” EUNSUNG-1033, 5:2-18.

332. In my opinion, a POSITA would have recognized a finite number of identified predictable solutions to maintain hygiene between patients (i.e., either sterilizing or replacing the treatment tip between patients), and it would have been obvious to try using a detachable tip that can be either removed and sterilized or disposed of and replaced between patients.

333. A POSITA would have recognized the benefit of using a disposable tip so that a sterilizing device, such as an autoclave, is not required to prepare the handpiece for use between patients. Alternatively, a POSITA would have appreciated the benefit of sterilizing a reusable, detachable tip, as opposed to the entire handpiece, so that a smaller autoclave may be used and that a clean tip could

be affixed to the handpiece while the used tip is being sterilized—thus minimizing downtime between uses.

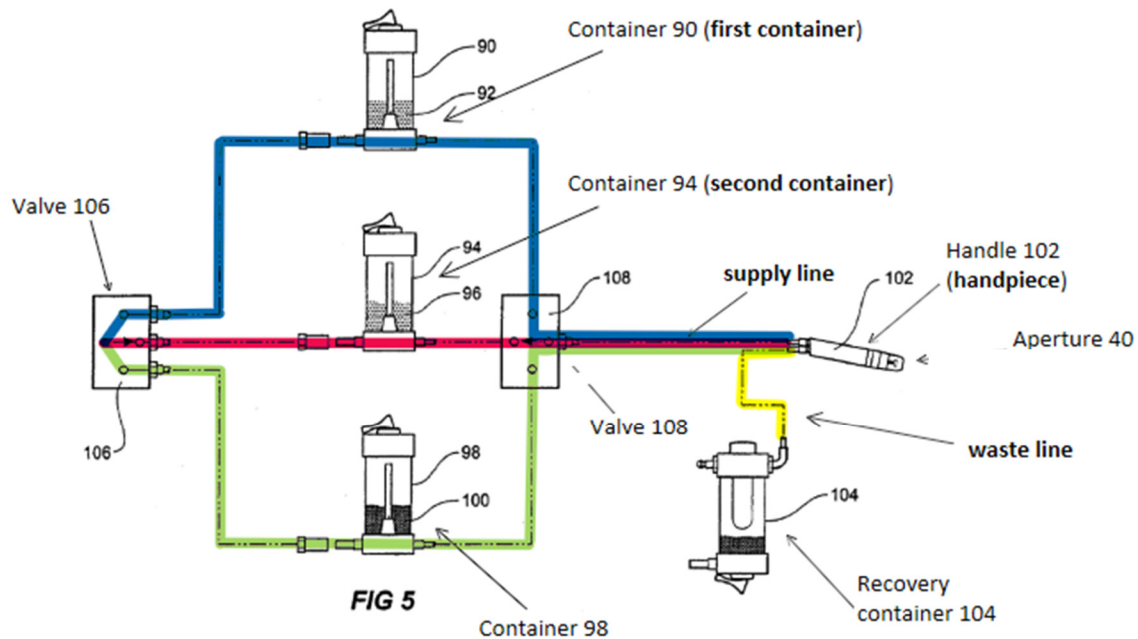
334. A POSITA would have found it obvious to couple the detachable tip with the body of handle 16/102 using known methods such as a friction fit or threading. *See, e.g.*, EUNSUNG-1004, [0047]. Thus, Greenberg renders obvious a handpiece (e.g., handle 16/102) configured to couple (e.g., through a friction fit) to a tip (e.g., end of handle 16/102 with aperture 40) that can be pressed against skin to perform skin treatment (e.g., microdermabrasion).

[1.3] a supply line connected between the handpiece and the console for sequentially delivering treatment material to the handpiece from the first container or the second container;

335. It is my opinion that Greenberg renders obvious a supply line (e.g., tube 20) connected between the handpiece (e.g., handle 16/102) and the console (e.g., apparatus 10) for sequentially delivering treatment material (e.g., standard aluminum oxide particles 92 or organically coated aluminum oxide particles 96) to the handpiece from the first container (e.g., container 90) or the second container (e.g., container 94).

336. As discussed in § X.5, FIG. 5's implementation would have been readily incorporated into FIG. 1's apparatus. As shown in FIG. 5, Greenberg's system includes "valve 108" configured to selectively connect one of supply containers 90, 94, 98 to handle 102 depending on which container is selected via

valve 106. EUNSUNG-1006, [0077] (“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 than connects that supply container to the handle 102 and recovery container 104.”). Therefore, Greenberg’s valve 108 selectively receives treatment material from the respective supply containers 90, 94, 98 when these containers are respectively selected to receive air flow thereinto (e.g., blue, red, and green paths in annotated FIG. 5).



Greenberg, FIG. 5 (annotated)

337. Although FIG. 5 does not label the path (dotted line) between the valve 108 and the handle 102, it would have been obvious that it is defined by a

tube, such as the tube 20 illustrated in FIG. 1, and this tube forms a “supply line”

within the meaning of element [1.3]. EUNSUNG-1004, [0049], FIG. 1.

Specifically, Greenberg discloses:

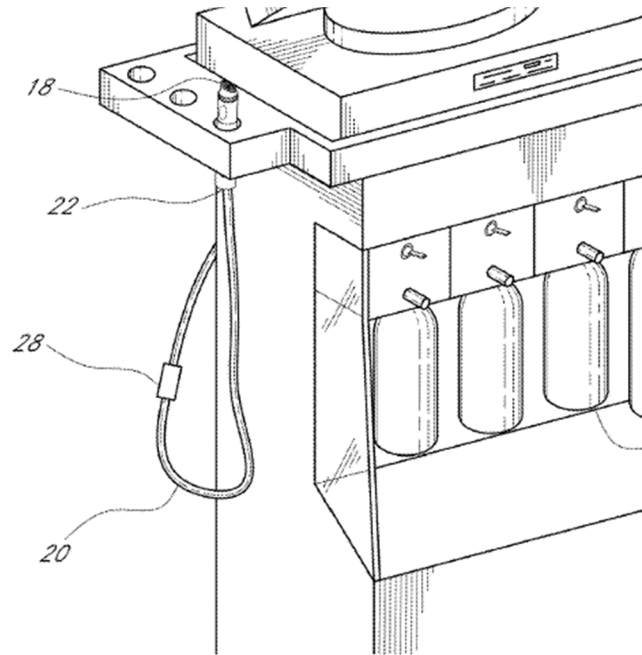
[0049] Turning now to the figures in detail, and specifically FIGS. 1 and 2, there is shown an apparatus 10 for making abrasions including **a vacuum pump 12 operatively connected in series to either a first assembly including a recovery container 14, a handle 16 and a supply container 18 by tubes 20**, or operatively connected to a second assembly including a recovery container 22, a handle 24 and a supply container 26 by tubes 28.

EUNSUNG-1006, [0049].

338. Moreover, as discussed in § X.5 and limitation 1.1 above, the valve system and containers 90, 94, 98 are received in apparatus 10. Because the supply line connects to valve 108 and the containers stored in apparatus 10, a POSITA would have understood that Greenberg’s supply line is “connected between” Greenberg’s handle 16/102 and apparatus 10.

339. This aligns with the disclosure of the ’607 patent. The ’607 patent states that line 20, which includes the supply line/input line 52 and waste line/output line 50, “is configured to provide fluid communication between the containers 26 and the handpiece assembly 18.” EUNSUNG-1001, 5:64-66; *see also id.*, 19:29-59. “The line 20 can comprise one or more conduits extending between the console 12 and the handpiece assembly 18.” *Id.*, 5:66-6:1. The ’607 patent does not describe nor depict either line connecting to an intermediate

component, such as a port or receiver, on the console. *See id.*, 5:64-6:13, 19:29-59, FIGS. 1, 16.



'607 Patent, FIG. 1 (excerpt)

340. I have been asked to consider whether it would have been obvious to a POSITA system to connect Greenberg's supply line to an intermediate component located within or upon apparatus 10, such as a port or receiver on apparatus 10, before then connecting to other components located within or upon apparatus 10. I believe it would have been obvious to a POSITA to connect Greenberg's supply line to an intermediate component located within or upon apparatus 10 for similar reasons to those explained above in Ground 1A. *See* § XI.2.

341. Additionally, Greenberg describes that "the apparatus contains separate abrasive and fragrant particles and that a user is firstly treated with the

highly abrasive particles and **subsequently** with the organic ones that assist in leaving a residual layer on the skin.” EUNSUNG-1006, [0084]. “For example, one may first wish to be treated with a harsh particle to remove quickly and efficiently top surface skin layers,” and “[s]**ubsequently** one may wish to use the gentler but still slightly abrasive organic particles that compensate for any serious abrasion whilst imparting to the skin substances that help protect and nourish it.” EUNSUNG-1006, [0089]. Greenberg discloses an example where the system can choose from three different treatment materials, including (a) purely organic materials, (b) a mixture of abrasive particles such as aluminum oxide mixed with organic materials, and (c) abrasive particles that are coated with organic materials. EUNSUNG-1006, [0072]-[0077].

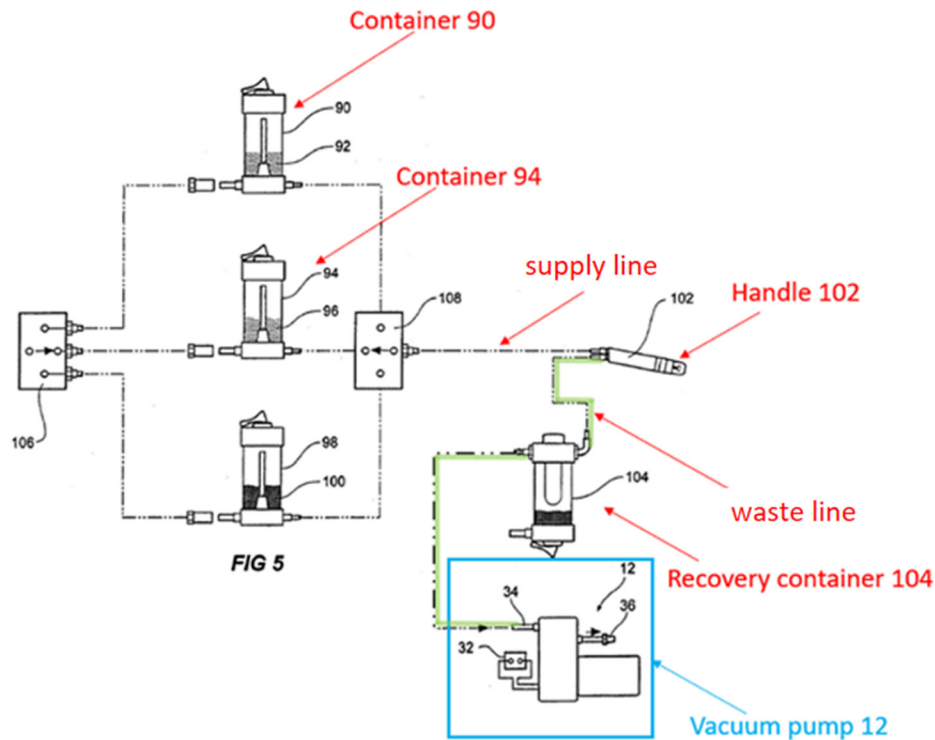
342. Thus, Greenberg renders obvious a supply line (e.g., tube 20) connected between the handpiece (e.g., handle 16/102) and the console (e.g., apparatus 10) for sequentially delivering treatment material the handpiece from the first container (e.g., container 90) or the second container (e.g., container 94).

[1.4] a waste line connected between the handpiece and the console; and

343. It is my opinion that Greenberg render obvious a waste line (e.g., tube 28) connected between the handpiece (e.g., handle 16/102) and the console (e.g., apparatus 110).

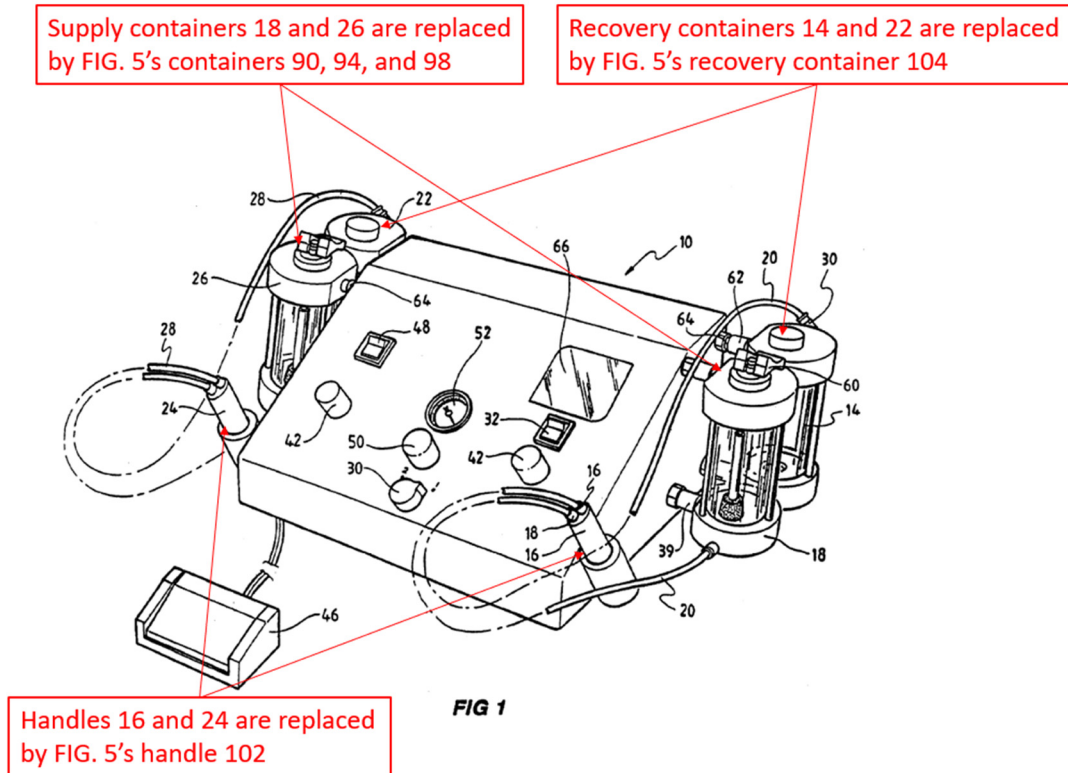
344. As shown in Modified FIG. 5 below, Greenberg’s handle 16/102 is

connected to recovery container 104 and vacuum pump 12. Although FIG. 5 does not label the path (dotted line annotated in green below) between the handle 102 and recovery container 104 and vacuum pump 12, it would have been obvious that this is defined by a tube, such as tube 28 illustrated in FIG. 1, and this tube forms a “waste line” within the meaning of limitation 1.4. EUNSUNG-1006, [0049], [0052], [0066]-[0067], [0077].



Greenberg, Modified FIG. 5

345. As above with respect to limitation 1.1, Greenberg’s recovery container 104 and vacuum pump 12 are stored in apparatus 10.

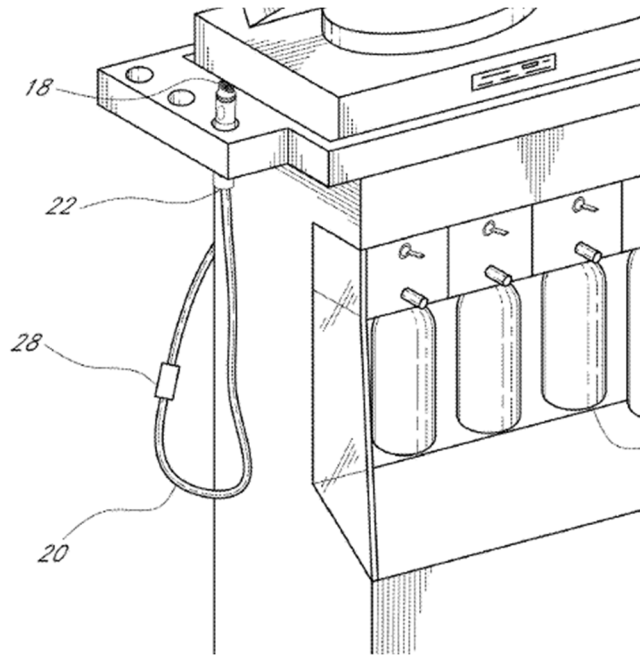


Greenberg, FIG. 1 (annotated)

346. Because the waste line connects to recovery container 104 and vacuum pump 12 stored within or upon apparatus 10, a POSITA would have understood that Greenberg's supply line is "connected between" Greenberg's handle 16/102 and apparatus 10.

347. This aligns with the disclosure of the '607 patent. The '607 patent states that line 20, which includes the supply line/input line 52 and waste line/output line 50, "is configured to provide fluid communication between the containers 26 and the handpiece assembly 18." EUNSUNG-1001, 5:64-66; *see also id.*, 19:29-59. "The line 20 can comprise one or more conduits extending

between the console 12 and the handpiece assembly 18.” *Id.*, 5:66-6:1. The ’607 patent does not describe nor depict either line connecting to an intermediate component, such as a port or receiver, on the console. *See id.*, 5:64-6:13, 19:29-59, FIGS. 1, 16.



’607 Patent, FIG. 1 (excerpt)

348. I have been asked to consider whether it would have been obvious to a POSITA to connect Greenberg’s waste line to an intermediate component located within or upon apparatus 10, such as a port or receiver on apparatus 10, before then connecting to other components located within or upon apparatus 10. I believe it would have been obvious to a POSITA to connect Greenberg’s waste line to an intermediate component located within or upon apparatus 10 for similar reasons to those explained above in Ground 1A. *See* § XI.2.

[1.5] a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is pressed against skin.

349. It is my opinion that Greenberg renders obvious a vacuum source (e.g., vacuum pump 12) configured to create a vacuum that draws waste material from the handpiece (e.g., handle 16/102) through the waste line (e.g., tube 28) for disposal (e.g., in recovery container 104) and that draws treatment material (e.g., standard aluminum oxide particles 92 or organically coated aluminum oxide particles 96) from either the first container (e.g., container 90) or the second container (e.g., container 94) to the handpiece when the tip (e.g., end of handle 16/102 with aperture 40) is pressed against skin.

350. Greenberg discloses that “the pneumatic source is a vacuum pump” (EUNSUNG-1006, [0026], [0004], [0049]-[0059], [0066]) and “said pneumatic source provides for an air flow through the recovery container, hand tool and the selected supply container in communication with same, drawing said particles from the supply container through the hand tool and into the recovery container.”

EUNSUNG-1006, [0017], FIG. 3, [0052]. Greenberg further explains that:

In operation, the vacuum pump draws air through either one of the assemblies and the corresponding recovery container and handle. **The handle includes an aperture 40, which is positioned against the surface to be treated, and which then causes air and thus particles to be drawn from the corresponding [supply] container.** The stream of particles then impinges on the surface against which the aperture is positioned

causing micro-abrasions and is subsequently drawn into the recovery container together with any abraded surface debris.

EUNSUNG-1006, [0052].

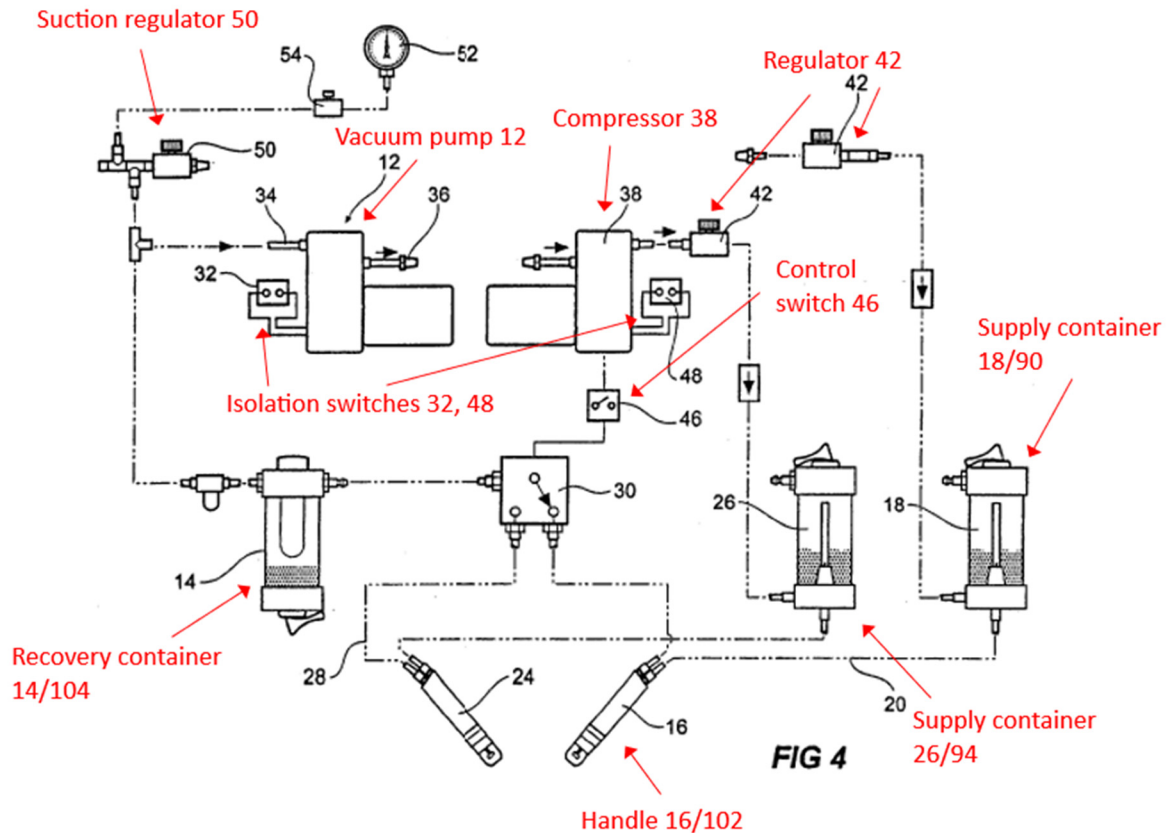
351. Thus, it would have been obvious that in FIG. 5, Greenberg's vacuum pump 12 provides a suction through a recovery container (e.g., container 90, 94) and handle 16/102 which (1) draws treatment material (e.g., standard particles 94 or organic particles 96) from one of the three containers based on the configuration of valves 106, 108 (e.g., container 90 or container 94) to the handpiece via Greenberg's supply line, and (2) draws used treatment material and waste from the handpiece to recovery container 104 via Greenberg's waste line for disposal.

EUNSUNG-1006, [0052]-[0053].

2. Claim 3

[3] The system of claim 1, further comprising a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

352. It is my opinion that Greenberg renders obvious a flow rate controller (e.g., regulator 42, control switch 46, suction regulator 50, isolation switches 48 and 32) to adjust a flow rate of the first treatment material (e.g., standard particles 94) or the second treatment material (e.g., organic particles 96) to the handpiece (e.g., handle 16/102). I have identified four elements in Greenberg's system that I believe render obvious the claimed flow rate controller: regulator 42, control switch 46, suction regulator 50, and isolation switches 48 and 32.



Greenberg, FIG. 4 (annotated)

353. **First**, I believe that a POSITA would have understood Greenberg’s regulator 42 as corresponding to the claimed flow rate controller. Greenberg states that the supply containers include “an inlet 39 connected to a regulator 42 having an inlet 44 the regulator controlling the amount of air entering the supply container.” EUNSUNG-1006, [0053]. Greenberg explains that “[t]he air entering the supply container aerates the particles, with the magnitude of air flow providing control over the flux or density of particles drawn though the apparatus.” *Id.* In FIG. 5’s implementation, a POSITA would have readily appreciated that regulator

42 may be placed at any point in the supply line before reaching a supply container (e.g., before valve 106 or after valve 106 and before reaching a supply container).

Thus, a POSITA would have recognized regulator 42 as a flow rate controller because it adjusts the flux or density of particles drawn through the apparatus by varying the amount of air allowed to enter the supply container selected by valves 106 and 108.

354. *Second*, I believe that a POSITA would have understood Greenberg's control switch 46 as corresponding to the claimed flow rate controller. Greenberg explains that inlet of the supply containers may be connected to compressor 38, which provides pressure to the containers. EUNSUNG-1006, [0054]. When the compressor 38 is turned off, only the force of the suction generated by vacuum pump 12 draws the treatment material to the handpiece. But when "different or heavier particles" are used or "a greater degree of micro-abrasion" is necessary, compressor 38 can be turned on "to provide [] *greater flow rate* and particle density" compared to using the vacuum pump alone. *Id.*, [0056]. Greenberg explains that "control switch 46" may be used to control the speed and thus the pressure provided by compressor 38. *Id.*, [0054].

355. I note that in this configuration, compressor 38 does not replace vacuum pump 12; rather, vacuum pump 12 is still providing suction through the selected supply container and thus drawing treatment material to the handpiece

when the tip is pressed against the skin—it is simply assisted by compressor 38.

See EUNSUNG-1032, 1:60-62 (“When the two systems are combined the vacuum pump is “pulling” the air/crystal through the handpiece while the compressor is “pushing” air/crystal through the handpiece.”).

356. In FIG. 5’s implementation, a POSITA would have found it obvious to connect compressor 38 to the inlet of valve 106 to provide pressure into the selected supply container. Thus, a POSITA would have understood Greenberg’s control switch 46 as a flow rate controller, which adjusts the flow rate of the selected treatment material to handle 16/102 by varying the pressure provided by compressor 38 into the selected supply container.

357. *Third*, I believe that a POSITA would have understood Greenberg’s suction regulator 50 as corresponding to the claimed flow rate controller. Greenberg describes “a suction regulator 50 that controls the suction provided to the apparatus by the vacuum pump 12.” EUNSUNG-1006, [0057]. In FIG. 5’s implementation, a POSITA would have found it obvious to place suction regulator 50 at any point between vacuum pump 12 and aperture 40 of handle 16/102. In this way, suction regulator 50 adjusts both (1) the level of suction present in aperture 40—and thus applied to the treatment surface—and (2) the level of suction flowing through the supply container selected by valves 106 and 108—and thus the flow rate of the treatment material carried to the handpiece by the suction provided by

vacuum pump 12. As a result, a POSITA would have understood Greenberg's suction regulator 50 as a flow rate controller, which adjusts the flow rate of the selected treatment material to the handle 16/102 by varying the amount of suction provided by vacuum pump 12 to Greenberg's system as a whole.

358. ***Fourth***, I believe that a POSITA would have understood Greenberg's isolation switches 48 and 32 as corresponding to the claimed flow rate controller. Greenberg discloses isolation switches 48 and 32, which control the operation of compressor 38 and vacuum pump 12, respectively. EUNSUNG-1006, [0057]. A POSITA would have understood Greenberg's isolation switches 48 and 32 as flow rate controllers, which adjust the flow rate of the selected treatment material to the handle 16/102 by turning on or off the pressure or suction supplied to the selected supply container by the compressor or vacuum pump.

359. Thus, Greenberg renders obvious a flow rate controller (e.g., regulator 42, control switch 46, suction regulator 50, isolation switches 48 and 32) to adjust a flow rate of the first treatment material (e.g., standard particles 94) or the second treatment material (e.g., organic particles 96) to the handpiece (e.g., handle 16/102).

3. Claim 4

[4] The system of claim 3, wherein the flow rate controller is located on the handpiece.

360. It is my opinion that Greenberg renders obvious locating the flow rate

controller (e.g., suction regulator 50 or control switch 46) on the handpiece (e.g., handle 16/102).

361. **First**, a POSITA would have found it obvious to locate Greenberg's suction regulator 50 on handle 16/102. I believe that locating Greenberg's suction regulator 50 on handle 16/102 would have been an obvious design choice in view of the knowledge of a POSITA. A POSITA would have known that similar microdermabrasion systems in the prior art have similar flow rate controllers located on a handpiece.

362. For example, Waldron includes a flow control valve 52 and corresponding vent hole 50 on the handpiece of a dermabrasion system. EUNSUNG-1033, 5:41-52; *see* § X.3. A POSITA would have understood Waldron's flow control valve 52 and vent hole 50 as directly analogous to Greenberg's suction regulator 50. Although Greenberg does not explicitly describe suction regulator 50's design, based on the depiction of suction regulator 50 in FIG. 4 and the design of regulators in similar devices, a POSITA would have understood suction regulator 50 as "control[ling] the suction provided to the apparatus by the vacuum pump 12" by adjusting the amount of outside air to vent into the system. EUNSUNG-1006, [0057]; *see, e.g.*, EUNSUNG-1004, [0059]; EUNSUNG-1033, 5:42-52; EUNSUNG-1028, 13:66-14:35.

363. A POSITA would have appreciated that locating Greenberg's suction

regulator 50 on handle 16/102 would not result in any difference in the function of Greenberg's system, would be well within the knowledge and skill of a POSITA, and would yield expected results.

364. I further believe that it would have been obvious to a POSITA to try locating Greenberg's suction regulator 50 on handle 16/102. Because suction regulator 50 must be placed at some point in the vacuum loop between vacuum pump 12 and aperture 40, a POSITA would have recognized a finite number of identified, predictable locations to locate Greenberg's suction regulator 50: in apparatus 10 or on handle 16/102. Given these options, I believe that it would have been obvious to a POSITA to try locating suction regulator 50 on handle 16/102.

365. A POSITA also would have been motivated to locate Greenberg's suction regulator 50 on handle 16/102 to allow an operator to allow an operator to more easily adjust the level of suction applied to the treatment area. A POSITA would have appreciated that it is more accessible and convenient for an operator to adjust a flow rate controller mounted on a device that the operator is already holding than having to reach to a flow rate controller mounted in another location (e.g., on a console). *See, e.g., EUNSUNG-1033, 5:51-52* ("The [flow control] valve 52 can be configured to be a simple on/off control or variable *so that suction can be readily adjusted by the operator while performing the procedure.*").

366. A POSITA would have recognized the desirability of being able to

easily control the level of suction in the system while performing a microdermabrasion treatment because different treatment areas and patients may require varying levels of suction and treatment material to receive an effective treatment. *See* EUNSUNG-1031, 4 (“Certain areas, including scars or hyperpigmented skin, may require more aggressive treatment with additional passes, increased crystal flow, or greater vacuum.”). As I explained in § VII.A, reducing the level of suction may be necessary around the eyes and other delicate areas of the face and in accordance with the patient’s tolerance. EUNSUNG-1013, 85-86; *see also* EUNSUNG-1029, 4:50-52 (“The physician will learn from experience how to balance the pressure level to attain the desired level of suction against the patient’s skin.”). In my opinion, a POSITA would have understood that locating the flow rate controller on the handpiece is more convenient for the operator than placing it on a console and results in faster, more effective, and safer treatments.

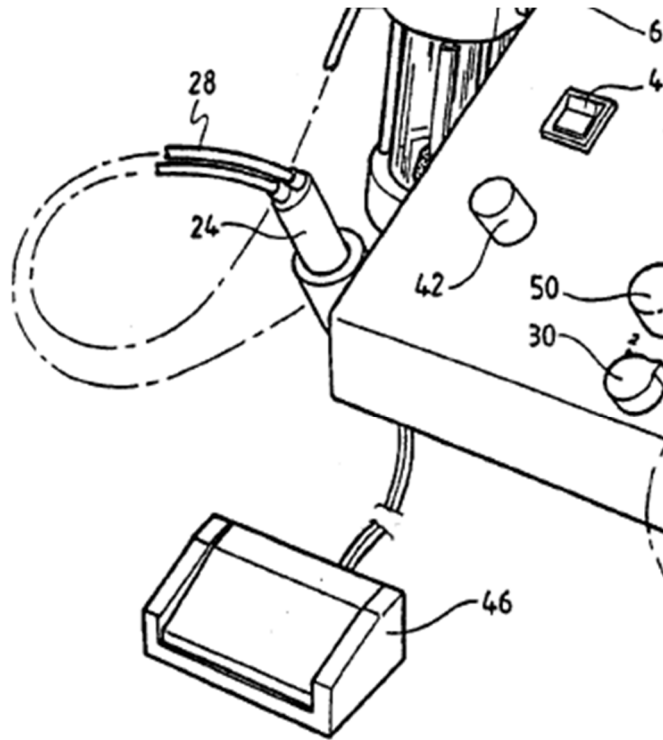
367. ***Second***, a POSITA would have found it obvious to modify Greenberg’s handle 16/102 to include control switch 46. A POSITA would have appreciated that in systems utilizing both a vacuum pump and a compressor, “the activation of the compressor becomes an issue.” EUNSUNG-1032, 1:66-67.

Greenberg describes one embodiment of control switch 46 as a foot pedal:

Advantageously, when the switch 30 operatively connects the vacuum pump with the second assembly, **control switch 46**,

***usually* a foot control switch, controls the compressor 38 to provide pressure to the supply container 26. The foot switch may be a variable switch that variably controls the speed and thus the pressure provided by the compressor.**

EUNSUNG-1006, [0054].

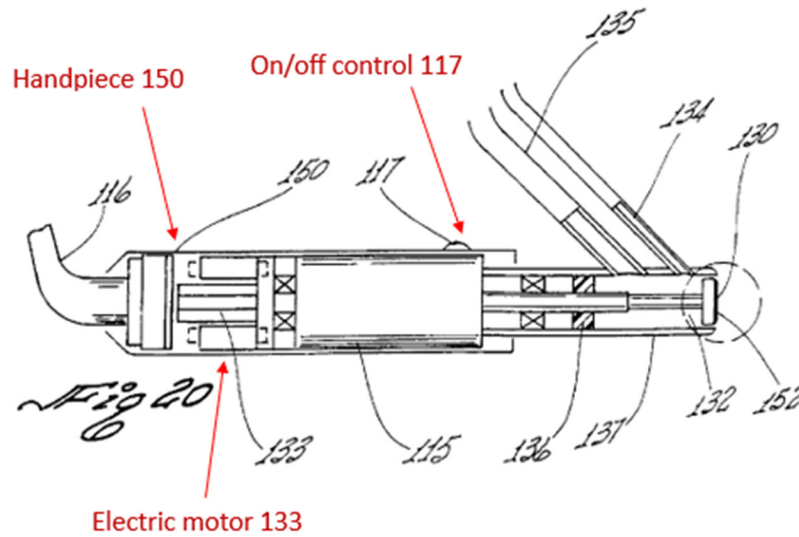


Greenberg, FIG. 1 (excerpt)

368. A POSITA would have understood Greenberg's disclosure as suggesting that control switch 46 may be placed in similar location readily accessible to an operator. Moreover, a POSITA would have recognized some drawbacks with using a foot pedal for as the control switch for activating compressor 38. *See, e.g.*, EUNSNG-1032, 1:33-36 ("The use of a footswitch is considered a drawback, as the operator requires good eye/foot coordination to

effectively control the compressor and the resulting stream of particles through the handpiece.”). A POSITA would have appreciated that a control switch located on a handpiece is a suitable alternative to a foot control switch. EUNSUNG-1033, 7:4-25 (recognizing a foot pedal as an alternative to a handpiece-mounted control switch). A POSITA would have found it obvious to use control switch 46 to control Greenberg’s compressor 38 through known methods, for example, an electrical wire or cord connected between the handle 16/102 and apparatus 10—such as the wire depicted in Greenberg FIG. 1 between control switch 46 and apparatus 10.

369. In my opinion, locating Greenberg’s control switch 46 on Greenberg’s handle 16/102 would have been an obvious design choice. A POSITA would have known that similar prior art microdermabrasion systems have control switches located on a handpiece. For example, Waldron discloses a handpiece with a rotating abrader. EUNSUNG-1033, 6:21-8:7. As depicted below in FIG. 20, handpiece 150 includes electric motor 133 to rotate abrader 132. *Id.*, 7:4-25. Electric motor 133 “is activated by the on/off control 117 mounted on the hand piece.” *Id.* Waldron states that “[a]n alternative is to use a foot pedal (not shown) to turn the motor on and off.” *Id.*



Waldron, FIG. 20 (annotated)

370. A POSITA would have appreciated that locating Greenberg's control switch 46 on handle 16/102 would not result in any difference in the function of the Greenberg's system, would be well within the knowledge and skill of a POSITA, and would yield expected results.

371. Locating Greenberg's control switch 46 on handle 16/102 also would have been obvious to try. A POSITA would have identified a finite number of predictable locations in Greenberg's system to locate control switch 46: on apparatus 10, on handle 102, or on a separate housing connected to compressor 38 (e.g., a foot switch). Given these options, I believe that it would have been obvious to a POSITA to try locating control switch 46 on handle 16/102.

372. A POSITA also would have been motivated to locate Greenberg's

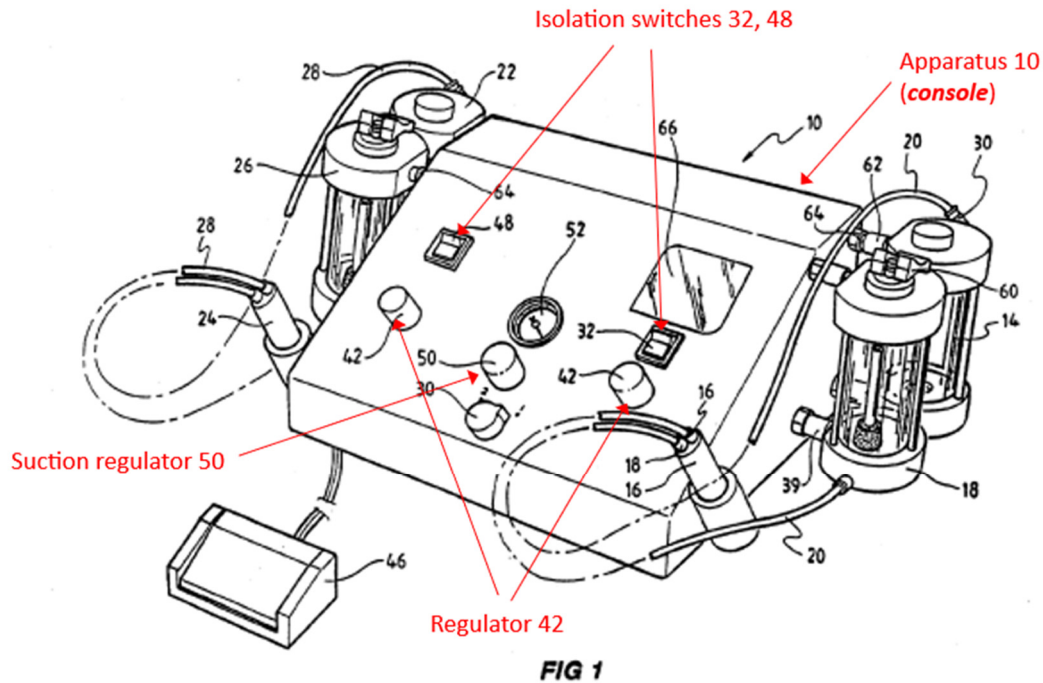
control switch 46 on handle 16/102—as opposed to, for example, a foot controller located in a separate housing—to reduce the total number of parts, and thus reduce manufacturing cost while improving operator control, allowing the flow rate “to be readily adjusted by the operator while performing the procedure.” EUNSUNG-1033, 5:50-52.

373. Thus, Greenberg renders obvious locating a flow rate controller (e.g., suction regulator 50 or control switch 46) on the handpiece (e.g., handle 16/102).

4. Claim 5

[5] The system of claim 3, wherein the flow rate controller is located on the console.

374. It is my opinion that Greenberg renders obvious a flow rate controller (e.g., suction regulator 50, inlet regulator 42, and isolation switches 48 and 32 as flow rate controllers) located on the console (e.g., apparatus 10). As depicted below in FIG. 1, Greenberg discloses that suction regulator 50, inlet regulator 42, and isolation switches 48 and 32 may be located on apparatus 10. EUNSUNG-1006, [0053]-[0055]; FIG. 1.



Greenberg, FIG. 1 (annotated)

375. Thus, Greenberg renders obvious a flow rate controller (e.g., suction regulator 50, inlet regulator 42, and isolation switches 48 and 32 as flow rate controllers) located on the console (e.g., apparatus 10).

XVI. [GROUND 2B] – Greenberg and Waldron

1. Claim 4

376. The combined teachings of Greenberg and Waldron render obvious claim 4 for the same reasons discussed above regarding Greenberg—i.e., that it would have been obvious to a POSITA to locate Greenberg's suction regulator 50 or control switch 46 on Greenberg's handle 16/102. It is my opinion that the combination of Greenberg and Waldron further renders obvious claim 4 based on

Waldron's teachings.

377. **First**, as discussed in § X.5, Waldron discloses a handpiece-mounted flow control valve 52 with a corresponding vent hole 50 for adjusting the level of suction in a vacuum line. A POSITA would have understood Waldron's flow control valve 52 and vent hole 50 as directly analogous to Greenberg's suction regulator 50. Although Greenberg does not explicitly describe suction regulator 50's design, based on the depiction of suction regulator 50 in FIG. 4 and the design of regulators in similar devices, a POSITA would have understood suction regulator 50 as "control[ling] the suction provided to the apparatus by the vacuum pump 12" by adjusting the amount of outside air to vent into the system—i.e., a breather/bleeder valve. EUNSUNG-1006, [0057]; *see, e.g.*, EUNSUNG-1004, [0059]; EUNSUNG-1033, 5:42-52; EUNSUNG-1028, 13:66-14:35.

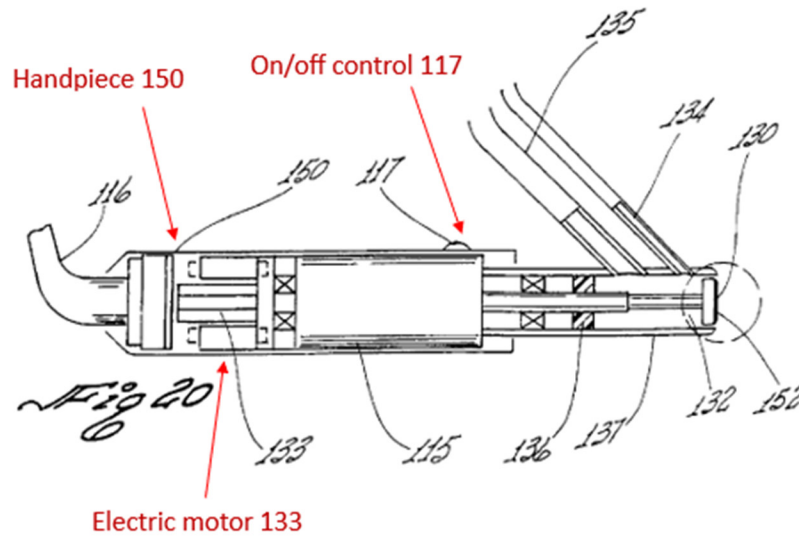
378. As I discussed above in § XV.3, a POSITA would have recognized the desirability of being able to easily control the level of suction in Greenberg's system while performing a microdermabrasion treatment and understood that locating a controller on the handpiece is more convenient for the operator than placing it on a console and results in faster, more effective, and safer treatments. A POSITA would have been motivated and found it obvious to replace Greenberg's suction regulator 50 with Waldron's handpiece-mounted flow control valve 52 (and corresponding vent hole 50) to allow an operator to more easily adjust the

level of suction applied to the treatment area.

379. A POSITA would have a reasonable expectation of success in replacing Greenberg's suction regulator 50 with Waldron's flow control valve 52 because Greenberg's suction regulator 50 and Waldron's flow control valve 52 function in a similar manner to achieve the same result.

380. Moreover, replacing Greenberg's suction regulator 50 with Waldron's flow control valve 52 would simply be the substitution of one known element (e.g., Greenberg's suction regulator 50) for another (e.g., Waldron's flow control valve 52) to achieve predictable results—i.e., a handpiece-mounted suction regulator. This combination would also reflect a use of a known technique to improve similar devices in the same way. Moreover, the combination is merely an application of a known technique to a known device ready for improvement.

381. ***Second***, as discussed in § X.5, Waldron also discloses a handpiece-mounted on/off control 117. Specifically, Waldron discloses a handpiece with a rotating abrader. EUNSUNG-1033, 6:21-8:7. As depicted below in FIG. 20, handpiece 150 includes electric motor 133 to rotate abrader 132. *Id.*, 7:4-25. Electric motor 133 “is activated by the on/off control 117 mounted on the hand piece.” *Id.* Waldron states that “[a]n alternative is to use a foot pedal (not shown) to turn the motor on and off.” *Id.*

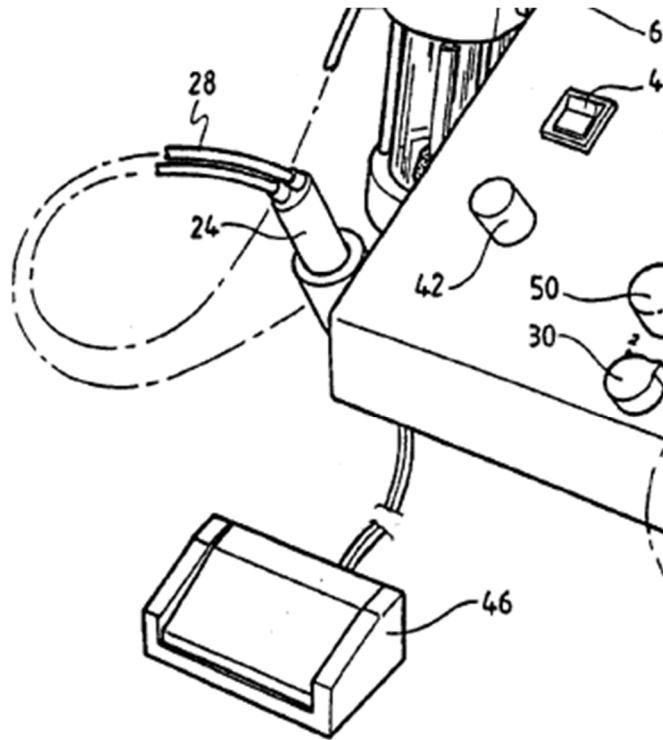


Waldron, FIG. 20 (annotated)

382. As I explained in § XV.3, a POSITA would have understood Greenberg’s statement that control switch 46 is “*usually* a foot control switch” and “*may be* a variable switch” as suggesting that control switch 46 may be implemented as an on/off switch somewhere other than a foot controller.

EUNSUNG-1006, [0054]. As I explained in § XV.3, a POSITA would have recognized drawbacks with using a foot pedal, benefits of using a handpiece-mounted control switch, and that a control switch located on a handpiece is a suitable alternative to a foot control switch. A POSITA would have been motivated and found it obvious to implement Greenberg’s control switch 46 (depicted in FIG. 1 as a foot controller) as Waldron’s on/off control 117 mounted on Greenberg’s handle 16/102.

383. A POSITA would have had a reasonable expectation of success in combining Waldron's on/off control 117 with Greenberg's system. For example, a POSITA would have found it obvious to locate Waldron's on/off control 117 on Greenberg's handle 16/102 and use on/off control 117 to control Greenberg's compressor 38 through known methods, for example, a wire connected between the handle 16/102 and apparatus 10—such as the wire depicted in Greenberg FIG. 1 between control switch 46 and apparatus 10.



Greenberg, FIG. 1 (excerpt)

384. Moreover, replacing Greenberg's control switch 46 with Waldron's on/off switch 117 would simply be the substitution of one known element (e.g.,

Greenberg's control switch 46) for another (e.g., Waldron's on/off switch 117) to achieve predictable results—i.e., a handpiece-mounted compressor control switch. This combination would also reflect a use of a known technique to improve similar devices in the same way. Moreover, the combination is merely an application of a known technique to a known device ready for improvement.

385. In the Greenberg-Waldron combination, a POSITA would have understood Waldron's flow control valve 52 and vent hole 50 and/or Waldron's on/off switch 117 as flow rate controllers for adjusting the flow rate of the selected treatment material to handle 16/102 for similar reasons I explained above with respect to Greenberg's suction regulator 50 and control switch 46. *See* § XV.2. Thus, the combined teachings of Greenberg and Waldron render obvious locating a flow rate controller (e.g., Waldron's flow control valve 52 or on/off switch 117) on the handpiece (e.g., handle 16/102).

XVII.[GROUND 2C] – Greenberg and Trueba

1. The Greenberg-Trueba Combination

386. In the Greenberg-Trueba combination, Greenberg's system would have been modified based on Trueba's teachings of computer control and display. For example, in the resulting system, Greenberg's valve 106 and/or valve 108 are further controlled by a computer (e.g., Trueba's controller 100), which is controlled by an user input (e.g., Trueba's touch screen 105), to control the flow of

treatment solutions from containers (e.g., Greenberg's containers 90, 94, and 98), so that a user can use the user input device to select a flow of fluids from the containers. The combined device also includes a display (e.g., Trueba's touch screen 105) that indicates which solution is being delivered.

387. A POSITA would have been motivated to modify Greenberg's device by including Trueba's computer control and display for various benefits, such as added precision, automation, and clarity. For example, by using Trueba's controller to control the order of different treatment materials (and displaying on the touch screen the material being administered), Greenberg-Trueba reduces the chance of applying treatment material in an undesired fashion. In fact, the same reasons that would have motivated the Karasiuk-Palmer-Trueba combination (Ground 1C) would similarly apply for the Greenberg-Trueba combination.

388. A POSITA would have had a reasonable expectation of success in implementing the combination given the technical similarities between Greenberg and Trueba. For example, similar to Greenberg, Trueba also discloses a system "for topical application of a bioactive composition to the surface of the subject, such as a patch of skin" EUNSUNG-1008, 3:22-27. Similar to Greenberg, Trueba also discloses a system that can select from different treatment materials from different containers. EUNSUNG-1008, 3:4-8, 5:14-26, 11:4-34, FIG. 3.

389. In addition, Trueba allows programming its system to deliver different

treatment materials at different times to allow automated delivery following complex administration protocols. EUNSUNG-1008, 3:34-38, 4:65-5:17, 6:1-9, 6:27-7:9, 10:52-11:49, FIG. 1. In addition to added automation and precision, Trueba's techniques also are beneficial because "[c]omputerized control of medication dosing, which may be programmed by medical personnel for subsequent automated delivery, can help avoid toxic drug interactions, overdoses, and death." EUNSUNG-1008, 6:1-9. For example, Trueba's system can be "programmed to prevent unauthorized alteration of dosages, for example an increase in a dosage of a controlled substance above that authorized by the prescribing physician." EUNSUNG-1008, 12:2-5.

390. In addition, Trueba discloses sequential or simultaneous delivery of treatment fluids from the first container and at least one additional container: "[O]ne or more of the bioactive agents from the reservoirs 54, 56 can be delivered from dispenser 30. The multiple bioactive agents may be administered sequentially or simultaneously." EUNSUNG-1008, 11:21-24

391. By the Critical Date, computer (e.g., PLC) controlled fluid delivery systems were well-known. EUNSUNG-1007, FIG. 3; EUNSUNG-1008, FIG. 3; EUNSUNG-1015, Abstract. Comparing to manually controlled systems, computer controlled systems provide added precision and automation (e.g., automated delivery of a first treatment for a fixed time followed by a second treatment for a

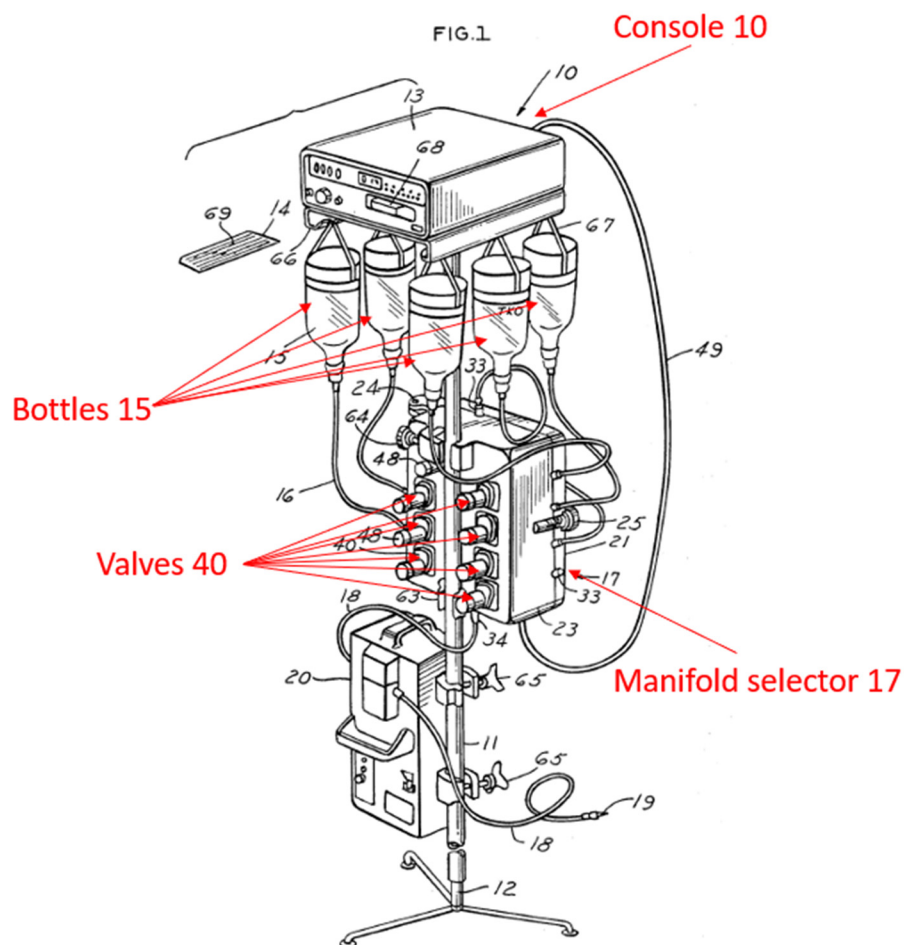
fixed time). EUNSUNG-1008, 11:4-34. Touch screen 105 “may include a series of images that, when touched with a finger or stylus, program the controller 100,” (EUNSUNG-1008, 11:50-59, FIG. 3) and can be used to “indicate which selections have been made” and to display “information such as desired dosages, frequency, and potential side effects.” EUNSUNG-1008, 11:42-49, FIG. 3; EUNSUNG-1014, Abstract, 1. Further, the touch screen can be operated to select a particular drug or dosage, or to program the controller. EUNSUNG-1008, 11:60-12:8.

392. A POSITA would have been motivated to modify Greenberg’s device by including Trueba’s computer control and display to provide added precision, automation, and clarity. A POSITA would have implemented the display and computer control with a reasonable expectation of success because this would constitute the use of a known technique to improve similar devices in the same way. In fact, the modification requires nothing more than automating the manual process in Greenberg with well-known automation techniques.

393. For example, Duchon discloses: “computer 100 controls valve motor 130 through motor driver 132, and monitors position through a Position Monitor feedback signal from potentiometer 134.” EUNSUNG-1010, [0098]. As another example, Greenberg discloses: “Switch 30 controls a solenoid that switches the vacuum pump from operatively being connected either to the first or second assembly.” EUNSUNG-1006, [0050]. As another example, Armstrong discloses

“the rotary selector valve 74 can be provided with a pulse activated solenoid driven stepping mechanism (not shown) such that the activation of a selector switch (not shown) on the handpiece advances the valve in a step-by-step manner to valve the desired fluid on a one step per pulse basis.” EUNSUNG-1011, 7:15-20. Thus, in the Greenberg-Trueba combination, a POSITA would have been motivated to implement Trueba’s computer control in various ways including by controlling Greenberg’s valve 106 and valve 108 using a stepper motor or a solenoid.

394. As another example, Wunsch discloses an apparatus (e.g., console 10) for sequentially dispensing a plurality of solutions through a manifold (e.g., manifold selector 17) that is connected to each of the solutions to be administered. EUNSUNG-1020, Abstract, 7:39-56, 8:17-26, FIGS. 1-4. As shown in FIG. 1, the manifold selector 17 includes a plurality of valves 40, which control the flow of solution from the plurality of bottles 15. EUNSUNG-1020, 6:18-48, 7:16-56. In operation, the user can program the sequencer timer 13 to automatically operate the valves 40 to achieve automatic switching between different solutions and sequential delivery of different solutions. EUNSUNG-1020, 9:36-10:64. The valves 40 can be individually controlled by either reversible electric motors 48 or solenoids 59. EUNSUNG-1020, 6:18-26.



Wunsch, FIG. 1 (annotated)

395. In the Greenberg-Trueba combination, valve 106 and valve 108 are further controlled by a computer (e.g., Trueba's controller 100), which is controlled by a user input (e.g., Trueba's touch screen 105), to control the flow of treatment solutions from containers (e.g., containers 90, 94, and 98). The combined device also includes a display (e.g., Trueba's touch screen 105) that indicates which solution is being delivered.

2. Claims 1, 3-5

396. Greenberg-Trueba renders obvious claim 1 for the same reasons discussed regarding Greenberg. *See supra* § XV.1.

397. In my opinion, Greenberg further renders obvious limitation 1.3 based on Trueba's teachings. In particular, to the extent that the term "sequentially" is interpreted to require automatic switching between the delivery of treatment material from the first or second containers, Greenberg-Trueba renders this limitation obvious. EUNSUNG-1008, 3:4-8, 5:18-6:9, 6:10-16, 11:4-34, 12:2-9.

398. It is my opinion that a POSITA would have understood that the term "sequentially" only requires that treatment material from a first container and a second container be delivered one after another, as opposed to "simultaneously," and does not require automatic switching between containers. However, to the extent that this term is interpreted to require automatic switching between containers, this feature is obvious in view of knowledge of the POSITA. For example, Trueba discloses "[c]omputerized control of medication dosing, **which may be programmed by medical personnel for subsequent automated delivery**, can help avoid toxic drug interactions, overdoses, and deaths."

EUNSUNG-1008, 6:6-9. If the '607 patent requires the device to be capable of delivering treatment material from two or more containers either sequentially or simultaneously, Trueba allows this functionality: "[O]ne or more of the bioactive agents from the reservoirs 54, 56 can be delivered from dispenser 30. The multiple

bioactive agents may be administered sequentially or simultaneously.”

EUNSUNG-1008, 11:21-24. As another example, Wunsch discloses that the user can program the sequencer timer 13 to automatically operate the valves 40 to achieve automatic switching between different solutions and sequential delivery of different solutions. EUNSUNG-1020, 9:36-10:64.

399. To the extent that the term “sequentially” is interpreted to require automatic switching from a first container to a second container, the Greenberg-Trueba combination renders this limitation obvious.

400. Trueba discloses: “Multiple compositions can be dispensed simultaneously or sequentially.” EUNSUNG-1008, 11:4-5. For example, corticosteroid from reservoir 52 would be administered to a subject having stable reactive airway disease, but if symptoms persist, then the β -agonist from reservoir 50 also can be delivered (for example, in response to pressing an activation button or programming the applicator).” EUNSUNG-1008, 11:15-20. Trueba explains “[c]omputerized control of medication dosing, **which may be programmed by medical personnel for subsequent automated delivery**, can help avoid toxic drug interactions, overdoses, and deaths.” EUNSUNG-1008, 6:6-9.

401. Using Trueba’s computer control, multiple compositions can be automatically dispensed simultaneously or sequentially. EUNSUNG-1008, 3:4-8, 5:18-6:9 (“Several modules may contain the same or different bioactive

compositions”), 6:10-16 (“may be used to apply the agent to an area of skin for topical application of a bioactive composition”), 11:4-34 (“Multiple compositions can be dispensed simultaneously or sequentially”). Further, the device can be programmed to respond to changing clinical circumstances. EUNSUNG-1008, 11:15-20 (“For example, only the corticosteroid from reservoir 52 would be administered to a subject having stable reactive airway disease. However, if symptoms persist, then the β -agonist from reservoir 50 also can be delivered.”). Further, the device can be programmed to “prevent unauthorized alteration of dosages” and “permit certain ranges of dosages to be administered.” EUNSUNG-1008, 12:2-9.

402. As discussed above in § XVII.1, Greenberg-Trueba’s system employs “[c]omputerized control of medication dosing, which may be programmed by medical personnel for subsequent automated delivery,” as taught by Trueba. EUNSUNG-1008, 6:6-9. A POSITA would have found it obvious to employ Trueba’s automation in Greenberg’s system to provide added precision (avoiding human error), automation, and clarity, resulting in automatic switching and delivery of treatment material in a sequential manner.

403. As discussed above in § XVII.1, in the Greenberg-Trueba combination, Trueba’s controller 100 is configured to control the delivery of treatment material to provide added precision, automation, and clarity. Thus, the

Greenberg-Trueba combination renders this limitation obvious. Similarly, dependent claims 2-10 that inherit the same subject matter are rendered obvious by Greenberg-Trueba.

3. Claim 2

[2.pre] The system of claim 1, further comprising:

[2.1] a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece, wherein the flow rate controller is located on the handpiece or on the console; and

404. For the reasons discussed above with respect to claim 3, I believe that the combination of Greenberg and Trueba renders obvious a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

405. For the reasons discussed above with respect to claim 4, I believe that the combination of Greenberg and Trueba renders obvious locating the flow rate controller on the handpiece.

406. For the reasons discussed above with respect to claim 5, I believe that the combination of Greenberg and Trueba renders obvious locating the flow rate controller on the console.

[2.2] a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

407. For the reasons discussed below with respect to claim 7, I believe that the combination of Greenberg and Trueba renders obvious a user input device to

select the first treatment material or the second treatment material for delivery to the handpiece.

4. Claim 6

[6] The system of claim 1, further comprising a computing device configured to control at least one function of the system.

408. It is my opinion that the Greenberg-Trueba combination renders obvious a computing device (e.g., Trueba's controller 100) configured to control at least one function of the system (e.g., delivery of treatment material). As discussed in § XVII.1, the Greenberg-Trueba combination includes a computing device (e.g., Trueba's controller 100) configured to control at least one function (e.g., delivery of treatment material) of the system. EUNSUNG-1008, 3:34-38, 4:65-5:17, 6:1-9, 6:27-7:9, 10:52-11:49, 12:2-5, FIG. 1.

5. Claim 7

[7] The system of claim 1, further comprising a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

409. It is my opinion that the Greenberg-Trueba combination renders obvious a user input device (e.g., Trueba's touch screen 105) to select the first treatment material (e.g., standard aluminium oxide particles 92) or second treatment material (e.g., organically coated aluminium oxide particles 96) for delivery to the handpiece (e.g., Greenberg's handle 16/102). As discussed above in § XVII.1, the Greenberg-Trueba combination includes a user input device (e.g.,

Trueba's touch screen 105) to select the first treatment material or the second treatment material for delivery to the handpiece. EUNSUNG-1008, 11:42-12:8, FIG. 3.

6. Claim 8

[8] The system of claim 7, wherein the user input device comprises a touch screen.

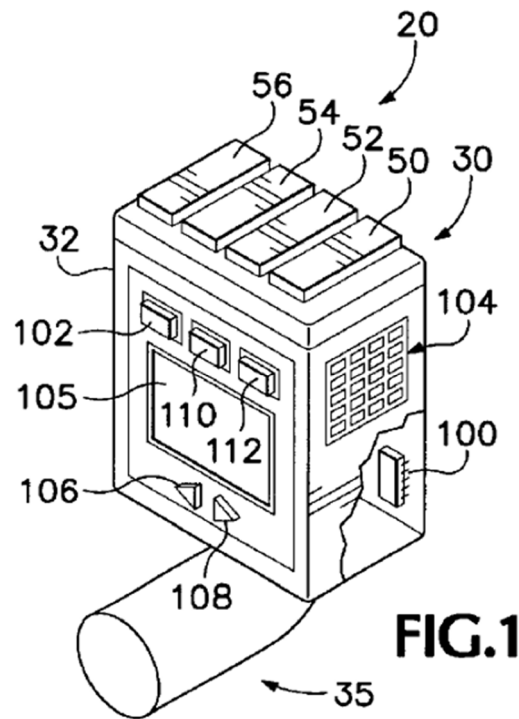
410. It is my opinion that Greenberg-Trueba renders obvious that the user input device (e.g., Trueba's touch screen 105) comprises a touch screen. As discussed above in § XVII.1, in the Greenberg-Trueba combination, the system comprises a touch screen (e.g., Trueba's touch screen 105) to select the first treatment material or the second treatment material for delivery to the handpiece. EUNSUNG-1008, 11:40-12:8, FIG. 3.

7. Claim 9

[9] The system of claim 7, wherein the user input device is positioned on the console.

411. It is my opinion that the Greenberg-Trueba combination renders obvious positioning a user input device (e.g., Trueba's touch screen 105) on a console (e.g., apparatus 10).

412. Trueba's exemplary embodiment is a handheld pulmonary inhaler, in which containers 50-56, ejection heads 40-46, controller 100, and touch screen 105 are contained within body 32 of applicator 30. EUNSUNG-1008, 10:52-12:8; FIG. 1.



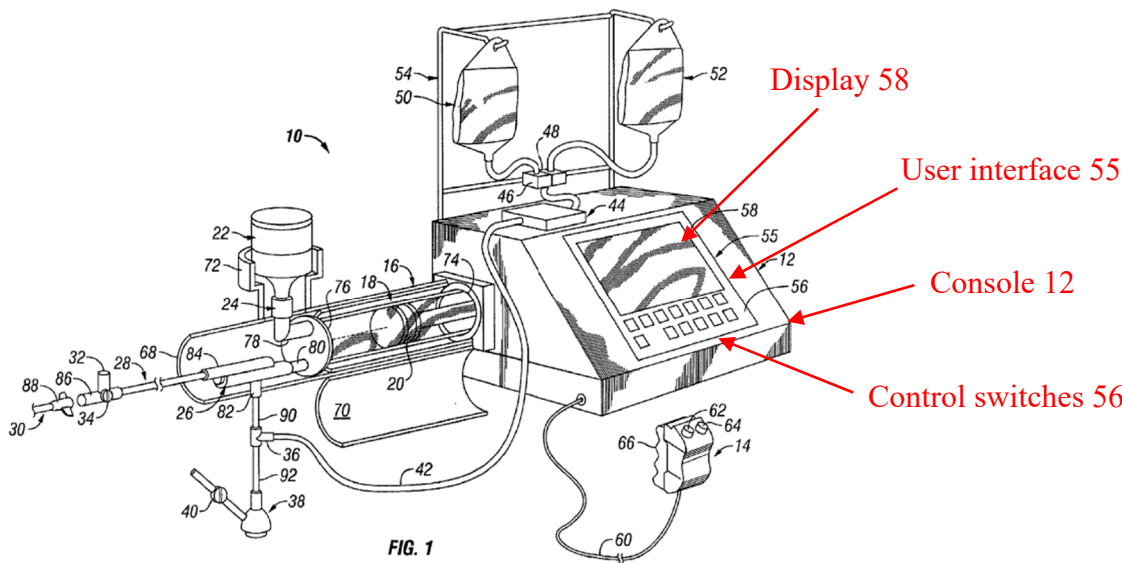
Trueba, FIG. 1

413. But Trueba also suggests alternative embodiments “for topical application of a bioactive composition to the surface of the subject, such as a patch of skin, rather than delivering the composition to a mucous membrane via a body orifice.” EUNSUNG-1008, 3:22-27. A POSITA would have recognized that for such an alternative use, e.g., delivering treatment material to a skin surface, a larger volume of or different, heavier treatment material may be required. A POSITA would have further recognized that locating Trueba’s containers 50-56, ejection heads 40-46, controller 100, and touch screen 105 within body 32 of applicator 30 may cause the applicator to become too large and unwieldy to handle

when used with a larger volume or heavier treatment material than that used in the disclosed pulmonary inhaler embodiment.

414. Therefore, for use in different embodiments, a POSITA would have recognized that it would be advantageous to place Trueba's containers 50-56, ejection heads 40-46, controller 100, and touch screen 105 in a separate location from the body 32 of applicator 30, such as in a console. In the Greenberg-Trueba combination, a POSITA would have found it obvious to position Trueba's touch screen 105 on Greenberg's apparatus 10 for several reasons. In fact, the same reasons that would have motivated a POSITA to position Trueba's touch screen 105 on Palmer's mobile cart 170 (Ground 1C) would similarly motivate a POSITA to position Trueba's touch screen 105 on Greenberg's apparatus 10. *See* § XIII.7.

415. ***First***, positioning a user input device like Trueba's touch screen 105 on a console was well-known and would have been within a POSITA's general knowledge. For example, Duchon discloses a system for injecting radiographic contrast material into a blood stream that includes a console 12 with a user interface 55 (e.g., control switches 56 and display 58) for controlling the system (e.g., the flow rate of the injection). EUNSUNG-1010, [0063], [0111]; FIG. 1.



Duchon, FIG. 1 (annotated)

416. In my opinion, a POSITA would have found it obvious to position Trueba's touch screen 105 on Greenberg's apparatus 10 as it was a known location to house a user input device in the prior art and the and the resulting system would have been predictable. This arrangement would also reflect a use of a known technique to improve similar devices in the same way. Moreover, this arrangement is merely an application of a known technique to a known device ready for improvement.

417. **Second**, it my opinion that a POSITA would have been motivated to position interconnected devices with each other to reduce manufacturing complexity and cost. As discussed in § XVII.1, Trueba's touch screen 105 interfaces with controller 100 to control the operation of Greenberg's valves 106

and 108, which are located in Greenberg's apparatus 10. A POSITA would have found it obvious to position those devices in the same location—i.e., in Greenberg's apparatus 10.

418. **Third**, I believe that positioning Trueba's touch screen 105 on Greenberg's apparatus 10 would have been obvious to try. A POSITA would have recognized a finite number of identified, predictable locations to locate Trueba's touch screen 105 in the Greenberg-Palmer system: either on Greenberg's handle 16/102 or on Greenberg's apparatus 10. Given these options, I believe that it would have been obvious to a POSITA to try locating Trueba's touch screen 105 on Greenberg's apparatus 10.

419. **Fourth**, I believe that positioning Trueba's touch screen 105 on Greenberg's apparatus 10 would have been an obvious design choice. In my opinion, choosing to locate Trueba's touch screen 105 on Greenberg's apparatus 10 would not result in any difference in the function of the Greenberg-Trueba system and the resulting device would function as a POSITA would have expected.

420. Thus, the combined teachings of Greenberg and Trueba render obvious positioning the user input device (e.g., Trueba's touch screen 105) on the console (e.g., Greenberg's apparatus 10).

8. Claim 10

[10] The system of claim 1, wherein the console comprises a display.

421. It is my opinion that the Greenberg-Trueba combination renders obvious that the console comprises a display (e.g., Trueba's touch screen 105). For the reasons discussed above with respect to claim 9, in the Greenberg-Trueba combination, I believe that a POSITA would have found it obvious to position a display (e.g., Trueba's touch screen 105) on the console (e.g., Palmer's mobile cart 170).

9. Claim 11

422. Claim 11 claims similar subject matter recited in claims 1 and 6.

[11.pre] A skin treatment system, comprising:

423. For similar reasons discussed above with respect to limitation 1.pre, I believe that the combined teachings of Greenberg and Trueba render obvious a skin treatment system.

[11.1] a console configured to receive a first container containing a first treatment material and a second container containing a second treatment material;

424. For similar reasons discussed above with respect to limitation 1.1, I believe that the combined teachings of Greenberg and Trueba render obvious a console configured to receive a first container containing a first treatment material and a second container containing a second treatment material.

[11.2] a handpiece configured to couple to a tip that can be placed against skin to perform skin treatment;

425. Claim 1's limitation 2 recites "a handpiece configured to couple to a tip that can be ***pressed*** against skin to perform skin treatment." In my opinion, a POSITA would not appreciate any difference between "pressed" and "placed" as it relates to the patentability of the '607 claims over the prior art discussed herein.

426. Thus, for similar reasons discussed above with respect to limitation 1.2, I believe that the combined teachings of Greenberg and Trueba render obvious a handpiece configured to couple to a tip that can be placed against skin to perform skin treatment.

[11.3] a supply line extending between the handpiece and the console for sequentially delivering treatment material to the handpiece from the first container or the second container;

427. Claim 1's limitation 3 recites "a supply line ***connected between*** the handpiece and the console for sequentially delivering treatment material to the handpiece from the first container or the second container." In my opinion, a POSITA would not appreciate any difference between "connected between" and "extending between" as it relates to the patentability of the '607 claims over the prior art discussed herein.

428. Thus, for similar reasons discussed above with respect to limitation 1.3, I believe that the combined teachings of Greenberg and Trueba render obvious a supply line extending between the handpiece and the console for sequentially

delivering treatment material to the handpiece from the first container or the second container.

[11.4] a waste line extending between the handpiece and the console;

429. Claim 1's limitation 4 recites "a waste line ***connected between*** the handpiece and the console." In my opinion, a POSITA would not appreciate any difference between "connected between" and "extending between" as it relates to the patentability of the '607 claims over the prior art discussed herein.

430. Thus, for similar reasons discussed above with respect to limitation 1.4, I believe that the combined teachings of Greenberg and Trueba render obvious a waste line extending between the handpiece and the console.

[11.5] a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is placed against skin; and

431. Claim 1's limitation 5 recites "a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is ***pressed*** against skin." In my opinion, a POSITA would not appreciate any difference between "pressed" and "placed" as it relates to the patentability of the '607 claims over the prior art discussed herein.

432. Thus, for similar reasons discussed above with respect to limitation

1.5, I believe that the combined teachings of Greenberg and Trueba render obvious a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is placed against skin.

[11.6] a computing device configured to control at least one function of the system.

433. For the reasons discussed above with respect to claim 6, I believe the combined teachings of Greenberg and Trueba render obvious a computing device configured to control at least one function of the system.

10. Claim 12

[12] The system of claim 11, further comprising: a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece, wherein the flow rate controller is located on the handpiece or on the console; and a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

434. Claim 12 claims similar subject matter recited in claim 2, which in turn claims similar subject matter recited in claims 3-5 and 7.

435. For similar reasons discussed above with respect to claim 3, I believe that the combination of Greenberg and Trueba renders obvious a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

436. For similar reasons discussed above with respect to claim 4, I believe

that the combination of Greenberg and Trueba renders obvious locating the flow rate controller on the handpiece.

437. For similar reasons discussed above with respect to claim 5, I believe that the combination of Greenberg and Trueba renders obvious locating the flow rate controller on the console.

438. For similar reasons discussed above with respect to claim 7, I believe that the combination of Greenberg and Trueba renders obvious a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

11. Claim 13

[13] The system of claim 11, further comprising a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

439. Claim 13 claims similar subject matter recited in claim 3. For similar reasons discussed with respect to claim 3, I believe that the combination of Greenberg and Trueba renders obvious a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

12. Claim 14

[14] The system of claim 13, wherein the flow rate controller is located on the handpiece.

440. Claim 14 claims similar subject matter recited in claim 4. For similar reasons discussed with respect to claim 4, I believe that the combination of

Greenberg and Trueba renders obvious the flow rate controller being located on the handpiece.

13. Claim 15

[15] The system of claim 13, wherein the flow rate controller is located on the console.

441. Claim 15 claims similar subject matter recited in claim 5. For similar reasons discussed with respect to claim 5, I believe that the combination of Greenberg and Trueba renders obvious the flow rate controller being located on the console.

14. Claim 16

[16] The system of claim 11, further comprising a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

442. Claim 16 claims similar subject matter recited in claim 7. For similar reasons discussed with respect to claim 7, I believe that the combination of Greenberg and Trueba renders obvious a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

15. Claim 17

[17] The system of claim 16, wherein the user input device comprises a touch screen.

443. Claim 17 claims similar subject matter recited in claim 8. For similar reasons discussed with respect to claim 8, I believe that the combination of Greenberg and Trueba renders obvious the user input device comprising a touch

screen.

16. Claim 18

[18] The system of claim 16, wherein the user input device is positioned on the console.

444. Claim 18 claims similar subject matter recited in claim 9. For similar reasons discussed with respect to claim 9, I believe that the combination of Greenberg and Trueba renders obvious the user input device being positioned on the console.

17. Claim 19

[19] The system of claim 11, wherein the console comprises a display.

445. Claim 19 claims similar subject matter recited in claim 10. For similar reasons discussed with respect to claim 10, I believe that the combination of Greenberg and Trueba renders obvious the console comprising a display.

18. Claim 20

446. Claim 20 claims similar subject matter recited in claim 1 and claim 2, which in turn claims similar subject matter recited in claims 3-5 and 7.

[20.pre] A skin treatment system, comprising:

447. For similar reasons discussed above with respect to limitation 1.pre, I believe that the combination of Greenberg and Trueba renders obvious a skin treatment system.

[20.1] a console configured to receive a first container containing a first treatment material and a second container containing a second treatment material;

448. For similar reasons discussed above with respect to limitation 1.1, I believe that the combination of Greenberg and Trueba renders a console configured to receive a first container containing a first treatment material and a second container containing a second treatment material.

[20.2] a handpiece configured to couple to a tip that can be pressed against skin to perform skin treatment;

449. For similar reasons discussed above with respect to limitation 1.2, I believe that the combination of Greenberg and Trueba renders obvious a handpiece configured to couple to a tip that can be pressed against skin to perform skin treatment.

[20.3] a supply line connected between the handpiece and the console for sequentially delivering treatment material to the handpiece from the first container or the second container;

450. For similar reasons discussed above with respect to limitation 1.3, I believe that the combination of Greenberg and Trueba renders obvious a supply line connected between the handpiece and the console for sequentially delivering treatment material to the handpiece from the first container or the second container.

[20.4] a waste line connected between the handpiece and the console;

451. For similar reasons discussed above with respect to limitation 1.4, I believe that the combination of Greenberg and Trueba renders obvious a waste line

connected between the handpiece and the console.

[20.5] a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is pressed against skin;

452. For similar reasons discussed above with respect to limitation 1.5, I believe that the combination of Greenberg and Trueba renders obvious a vacuum source configured to create a vacuum that draws waste material from the handpiece through the waste line for disposal and that draws treatment material from either the first container or the second container to the handpiece when the tip is pressed against skin.

[20.6] a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece, wherein the flow rate controller is located on the handpiece or on the console; and

453. For similar reasons discussed above with respect to claim 3, I believe that the combination of Greenberg and Trueba renders obvious a flow rate controller to adjust a flow rate of the first treatment material or the second treatment material to the handpiece.

454. For similar reasons discussed above with respect to claim 4, I believe that the combination of Greenberg and Trueba renders obvious locating the flow rate controller on the handpiece.

455. For similar reasons discussed above with respect to claim 5, I believe that the combination of Greenberg and Trueba renders obvious locating the flow

rate controller on the console.

[20.7] a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

456. For similar reasons discussed above with respect to claim 7, I believe that the combination of Greenberg and Trueba renders obvious a user input device to select the first treatment material or the second treatment material for delivery to the handpiece.

XVIII. [GROUND 2D] – Greenberg, Trueba, and Waldron

1. Claims 2, 4, 12, 14, 20

457. It is my opinion that the combined teachings of Greenberg, Trueba, and Waldron render obvious claims 2, 4, 12, 14, and 20 for the same reasons discussed regarding Greenberg-Trueba. I believe that the combination of Greenberg, Trueba, and Waldron further renders obvious claims 2, 4, 12, 14, and 20 based on Waldron’s teachings for similar reasons explained above with respect to Greenberg and Waldron.

XIX. CONCLUSION

458. In conclusion, I find the claims of the '607 patent addressed herein to be rendered obvious in their entirety, based upon the prior art combinations of Karasiuk-Palmer; Karasiuk-Palmer-Waldron; Karasiuk-Palmer-Trueba; Karasiuk-Palmer-Trueba-Waldron; Greenberg; Greenberg-Waldron; Greenberg-Trueba; Greenberg-Trueba-Waldron, and the supporting prior art of these combinations.

459. The findings and opinions set forth in this declaration are based on my work and examinations to date.

460. I may continue my examinations. I may also receive additional documentation and other factual evidence over the course of this IPR that will allow me to supplement and/or refine my opinions. I reserve the right to add to, alter, or delete my opinions and my declaration upon discovery of any additional information. I reserve the right to make such changes as may be deemed necessary.

461. In signing this declaration, I recognize that the declaration will be filed as evidence in an IPR before the PTAB. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

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

Dated: January 11, 2025

By: 
Eric Simon
Salt Lake City, Utah

APPENDIX A

Curriculum Vitae of **ERIC MICHAEL SIMON**

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 [linkedin.com/in/ericmsimon1](https://www.linkedin.com/in/ericmsimon1) |  [researchgate.net/profile/Eric_Simon](https://www.researchgate.net/profile/Eric_Simon)
 [facebook.com/dexterityproductdesign](https://www.facebook.com/dexterityproductdesign)
website esimonconsulting.com

Career Highlights

- ❖ Founder and Principal – President / Design Engineer – Dexterity Design: Product design and engineering services, prototyping, testing, pre-production services
- ❖ Founder and Chief Technologist – Acme Biosystems; R&D, production, and marketing of systems for 3-dimensional, high density, long-term culture of mammalian cells
- ❖ SwiftKey™ fastener – successfully conceived, prototyped, patented, marketed, and licensed product, currently licensed to MicroPlastics Inc.
- ❖ Co-Manager—Miniature Implantable Drug Delivery Systems Project (funded by Merck): Two patents issued; responsible for technical development, personnel management, budgeting, scheduling, reporting
- ❖ National Institute of Health SBIR Grant Principle Investigator—Fibrous Substrates for Cell Culture: First known use of polymeric electro-spun cell substrates and prelude to 3D scaffold culture
- ❖ Twenty-two patents issued & pending, including 4 pro se utility patents
- ❖ Numerous products designed, produced, and marketed

Experience

DESIGN ENGINEER / CONSULTANT

1995 to Present

Dexterity Design, Salt Lake City, Utah

- Product design and prototyping, engineering, testing and failure analysis, bridge to manufacturing
- Project management, market and patent research, expert witness services
- Focus on medical device, biotechnical, consumer, and recreational product sectors
- Recent and Current Projects:
 - ◆ Portable hand-held ventilator
 - ◆ Automated cell processing instrument with magnetic bead separation
 - ◆ DVT ultrasonic ablation system
 - ◆ Syringe aspiration accessory

- Prior Work: **Biosensors:** Nanopore proteomics, SPR proteomics, PCR rapid pathogen, TIRF Fluorescence; **Orthopedics:** Targetable needle-over-needle stem cell delivery (vertebral disc), ALIF Cage (vertebral fixation), Ti6 toe fixation implant and driver; **Dermatology:** Forced-air headlice treatment, LED- and Laser-based phototherapy, Micro-dermabrasion, Cellulite reduction; **Ophthalmic:** Topographic surface measurement for LASIK, Ophthalmic iontophoretic drug delivery; **Vascular:** Subclavian catheter sealing system; Bevel-tip cardiac catheter; Cardiac catheter incision closure, Venous blood pressure transducer; **Misc Med & Biotech:** Portable handheld ventilator, PCR hybridization automated wash, Ultrasonic probe, misc device enclosures, misc dental devices; **Non-Medical:** Ruggedized portable data-clock, Snowflake metrical instrument, Modular event canopy, Biometric time clock, Sport bottle, Modular crowd-control barrier, Drug-delivery port fluidic connector, Tool-less irrigation couplings, Modular climbing wall, Water-filled barriers, Pet toys, Sunglasses & ski goggles, Sport gloves.



Experience (continued)	SR. SYSTEMS ENGINEER / MICROFLUIDICS SPECIALIST		2018 to 2020
	Carterra, Inc., Salt Lake City, Utah		
	• Systems engineering, project management, constraint and risk analysis • Design and implementation of milli- and micro-fluidic systems • Design and implementation of proteomic biosensor instruments		
	FOUNDER / PRESIDENT / CHIEF TECHNOLOGIST		2005 to Present
	Acme Biosystems, Salt Lake City, Utah		
	• Invention and development of advanced gas-permeable cell culture systems • Project management, market research, patent prosecution • Management and strategic planning		
Prior Experience	PROJECT ENGINEER / BIOMATERIALS SPECIALIST		
	Center for Engineering Design, Salt Lake City, Utah Drug Delivery Devices, Cell Culture Systems, Micro Electromechanical Systems (MEMS), Abdominal Implants, Material and Design Consultation, Robotics, Technical and Grant Writing, Project Management		
	BIOMATERIALS / DEVELOPMENT ENGINEER		
	SynCardia Systems / Symbion Inc., Salt Lake City, Utah Artificial Heart Devices and Instrumentation		
	ZAMBONI OPERATOR		
Education	Sun Valley Ice Center, Sun Valley, Idaho Ice Sheet Maintenance and Refrigeration Systems		
	MANUFACTURING ENGINEER		
	American Medical Optics, Irvine, California Intraocular and Contact Lenses		
	Master of Engineering, Bioengineering, Biomaterials & Product Design, University of Utah		
	Bachelor of Science, Materials Science & Engineering, Biomaterials/Fabrication University of Utah		
Legal Experience	Mechanical Engineering / Premedicine, University of Michigan		
	Expert Witness - 13 cases total		
	Patent Infringement / Invalidation / Breach of Confidentiality - 4 cases		
	Personal Injury / Medical Malpractice - 9 cases		
	• Invalidation of phototherapy device patent via IPR • Infringement of gas-permeable cell culture device patents (litigation and IPR) • Invalidation of blood separation device patent • Infringement of specialty toothbrush and invalidation of patent • Failure of eyeglass frame resulting in permanent eye damage to consumer • Failure of embolic microspheres resulting in patient blindness and brain damage • Failure of heparin infusion pump resulting in patient death • Failure of implantable penile prosthesis (unrelated to prior case) • Failure of conventional hip implant • Failure of night light and subsequent hand injury • Failure of custom implantable hip prosthesis • Entanglement of hand in rotor assembly of vacuum blower • Failure of implantable penile prosthesis		
Professional Skills	Project Management Systems Engineering Budgeting & Scheduling Patent Review & Analysis Proposal Preparation Legal Expert Witness Market Review & Analysis		
	Mechanical & Product Design Prototyping / 3D Printing CAD/CAE - SolidWorks Design Review Product Styling & Ergonomics New Product Analysis KOL Interaction		
	Surface Characterization Materials Selection Surface Modification Molding & Fabrication Manufacturing Analysis Failure Modes Analysis Risk Analysis		

Product Scope	Drug Delivery Systems	Cardiovascular Devices	Ophthalmic Devices
	Fluidics and Microfluidics	Biosensors	Stem Cell Devices
	Cell Culture Products	Disposable Medical Products	Performance Apparel
	Percutaneous Access Devices	Dental Products	Micro Mechanisms/Sensors
	In Vitro Diagnostic Systems	Soft Goods	Device Enclosures/Housings
	Laboratory Products & Instruments	Sport Optics	Catheter-Based Devices
	Needle-based devices	Mounting Systems/Platforms	Instrument Subsystems
	Biomaterials Selection/Analysis	Recreational Products	Consumer Healthcare Products
Patents	Syringe Aspiration Accessory Device and Methods of Use (patent pending, US & EU Nat'l Phase)		
	Cell Culture Apparatus and Associated Methods (8,486,692; pro se prosecution)		
	Airflow Applicators and Related Treatment Methods (8,475,510)		
	Container and Lid (US design patent pending)		
	Airflow Attachment (D62687)		
	Time Clock (D622168)		
	Interlocking Barriers (7,275,888)		
	Interlocking Barrier (D552,250)		
	Detachable Clasp Fastener (6,243,922; pro se prosecution)		
	Control Barrier with Rotatable Legs (6,676,113)		
	Reusable Fluid Pressure Transducer Monitoring Apparatus (6,635,020)		
	Method and System for Performing Microdermabrasion and Suction Massage (6,926,681)		
	Method and System for Performing Microdermabrasion (6,582,442)		
	Dermabrasion Handpiece (D451,196); Dermabrasion System (D450,842)		
	Lens and Associatable Flow Cell (6,108,463 & 6,356,676 & 6,611,634; EP0928416;)		
	Interlocking Control Barrier Systems (6,086,285)		
	Waveguide Lens (D426,783)		
	Teeth Cleaning Implement with Integrated Fluid Dispenser (5,642,994)		
	Implantable Drug Delivery System with Piston Actuation (5,196,002 & 5,059,175)		
	Multiple Vesicle Implantable Drug Delivery System (5,167,625)		
	Disposable Toothbrush Cover (5,139,142; pro se prosecution)		
Technical Reports	History of Aspiration Devices and Centrifugation Vessels		
	History and Physics of Gas-Permeable Cell Cultureware		
	Technical Brief: CELLUXE Gas-Permeable Cell Culture System		
	Analysis of Metal Sintering System for Ti Toe Fixation Implants		
	Thermal Block Production Methods for the Olympia PCR Instrument		
	Site-Rite Clinical Evaluation Report		
	Product Design Assessment: Defective Reading Glasses		
	Findings: Pingle v. BioSphere Medical, Inc.		
	Effects of a Magnetic Fluid Mixture on Cells Cultured in ACCS		
	Ergonomic Analysis of Site-Rite Ultrasound Probe		
	Failure of Implantable Penile Prosthesis		
	Sealing System for a Long-Term Dialysis Catheter		
	Tipping Analysis of Water-Filled Barrier		
	Ophthalmic Electrode Materials Search		
	Search Report: Tube and Pipe Fittings		
	Manufacturing Feasibility for Production of Orlock™ Tubing		
	Design Specification: Passive Cartridge v1.1		
	Apollo™ Flashtube Chassis Design Verification		

Tech Reports
(continued)

Prophyze™ DDPA Pros & Cons
Optimization of Waveguide Signal-To-Noise Ratio
Implant Testing of Butyrate Sheet Subjects to Static Cling Vinyl Labels
Incompatibility of Static Cling Vinyl Labels with Ski Goggle Lenses
Brittle Failure of Cellulose Propionate Sheet
Surgical Microscope Shield—Concept Design & Materials
Plastics Recommendations for Modular Cellular Telephone
Discussion of Goggle Spacer-Foam Adhesion Failure
L.L. Bean Lens Abrasion—Results of Optical and Physical Analysis
Sunglass Frame Materials—Comparison of Properties
Alternative Plastic Materials for High Performance Sunglass Frames
Analysis and Performance Testing of the Snap Fit Assembly of a Night Light
Materials Recommendations for Adjustable Ski Pole Clamp
Sunglass Frame Redesign—Fortified Lens Groove
Sunglass Lens Failure—Hardcoat Delamination
Goggle Face-Foam Adhesion—Interim Report
Coating Durability of Plastic Sunglass Lenses—QA Specification
Rutherford Backscattering Analysis of Mirror Lens Coatings
Summary of Findings—Baxter v. Cincinnati Fan
Injection Molding, Embrittlement, and ESC of Sunglass Frames
Materials for Encapsulation of Transcutaneous Energy Transmission System
Polycarbonate Thermal Lens Fogging
Process Control for Thermoformed Lens Production
Crazing of L.L. Bean Sunglass Lenses
Environmental Stress Crack Failure of Ventilator Cartridge Tubing Connector
Redesign of Ventilator Cartridge and Coupline
Miniature Implantable Drug Delivery System—Phase II Final Report
Historical and Technical Review of Drug Delivery Systems
NIH SBIR Phase I Final Report: Fibrous Substrates for Cell Culture
A Review of the FLEX Series Displacement Sensors
Electret Materials: Preparation By Corona Discharge and Electron Bombardment
Preparation of Teflon Fibers for Electret Materials
Electrostatic Spinning of Solution Polymers: Design and Surface Characterization
Surface and Bulk analysis of Biomer® Polyurethane in Implanted Artificial Hearts
Review of Surface Passivation Technologies for Blood-Contact Materials
Polish Formulation and Finishing Methodology for IOL and Contact Lens Production
Review of IOL Haptic Design

Proposals

Development of a Novel Bone Marrow Fractionation and Isolation Device
Development and Testing of High Performance Plate-Based Cultureware, NIH SBIR
Reliable Central-Nervous-System Interfaces, DARPA
Medical Diagnosis Platform for Category A and B Toxins and Inhalation Bacteria
Rapid Diagnostics Platform for Category A and B Toxins and Inhalation Bacteria
Investigation of the Effects of a Magnetic Fluid Mixture on Mammalian Cells
Advanced System for Routine Primary Hepatocyte Culture, NSF SBIR
Proposal for Design and Dev't of an Anesthesia Rebreathing Absorber Module
Ophthalmic Electrode Materials
Development and IP Review of a Micro-Dermabrasion System

Proposals (continued)	Intermediate Waveguide: Overview and Development Budget
	Design and Prototype of a Custom Photo Station for AMS
	Design and Prototype of an Aesthetic Massage System
	RFQ: Multibarrier 1B Finite Element Analysis
	Test Fixtures for Fluorescence Immuno-Diagnostic System
	Plastic Enclosure for the Genesis-2000 Dental Laser System
	Disposable Dental Articulator
	Electrical Connection System for pH Enteral Feeding Catheter
	Dental Implant Surgical Guide
	Double-Blade Biopsy Knife
	Thermoformed Enclosure for Vibrotactile Tester
	Plastic Enclosure for the AccuCure 3000 Dental Laser System
	Materials & Analysis of Overmolded Ski Pole Grip
	Determination of Lens Surface Temperature
	Medical Device Introducer—Materials & Fabrication
	Porcelain Dispensing System for Dental Fabrication
	Heated Matched-Mold for Thermal Lens Production
	A Pet Collar Drug Delivery System
	MIDDS—University of Utah Biomedical Research Support Grant
	Thermal Energy Generation from Palladium Hydrolytic Cells
	MIDDS: A Miniature Implantable Drug Delivery System
	Fibrous Substrates for Cell Culture, NSF SBIR
	Fibrous Substrates for Cell Culture, NIH SBIR
	Subcutaneous Peritoneal Access Device: Review of Potential Development Projects
Specifications	ABE Field Ventilator: Mechanical and Housing Specification
	Gemini Protein Binding Biosensor
	CURIOSITY G2 Wireless Earbuds: Assembly and QC Specification
	Optical Module and Assembly for Crawling Robot
	Stem Cell Delivery Device: Design and Product Specification
	AcmeBio Test Plate: Rack + Lid Mold Specification
	Thermaflux Product Development Specification
	Design Specification: Site-Rite Ultrasound Probe Handle
	Head Lice Treatment Device
	Therapeutic Laser Handpiece Product Specification
	TIRF Diagnostic Device Cartridge and Instrument
	Portable Photo Booth Product Specification
	Cellulite Reduction System Design Specification
Business Documents	Syrasist™ Syringe Aspiration Accessory—Licensing Plan and Financial Analysis, in preparation
	Celluxe™ Advanced Cell Culture Products—Business Plan and Financial Analysis, 2015
	Quikey™ Rapid Key Link—Business and Licensing Plan and Financial Analysis, 1999
	Calapso™ Drinkware Products—Business Plan and Financial Analysis, 1994
	SportStax™ Production Financial Analysis, 1993
	VersaGlove™ High-performance Gloves—Business Plan and Financial Analysis, 1991

- Publications** Gergely M, Shkurko K, Simon E. A Novel Technique for Automated Mass Measurements of Individual Snowflakes (AGU A23A-0177). Poster presented at: the American Geophysical Union Fall Meeting; 12-16 December 2016; San Francisco, CA.
- Herron JN, Wang H-K, Tan L, Brown SZ, Terry AH, Durtschi JD, Simon EM, Astill ME, Smith RS, Christensen DA. Planar Waveguide Biosensors for Point-Of-Care Clinical and Molecular Diagnostics. In: Fluorescence Sensors and Biosensors (R. B. Thompson, Ed.). Marcel Dekker, New York, 2006. pp. 283-332.
- Simon E. "Be Careful with the 'Custom' Device Exclusion," SCOPE, 2(1), February 1995, p. 6.
- Citations** Petrik, S, et al., Chapter: Functional Nanofibers for Sensors, In book: Electrospinning – Material Technology of the Future, 2022, IntechOpen: <https://www.intechopen.com/books/11127>.
- Anstey A, et al., Nanofibrillated polymer systems: Design, application, and current state of the art. Prog. Polymer Sci, 113 (2020), Elsevier, New York, p. 2.
- Chapter 10 - Electrospun Nanofibrous Filtration Membranes for Heavy Metals and Dye Removal, in Nanoscale Materials in Water Purification - Micro and Nano Technologies, 2019, Elsevier, New York, p. 5.
- Marzioch, J, Microsensor System for the Metabolic Monitoring in Cancer Cell Culture, Doctoral Thesis, Albert-Ludwigs-Universität Freiburg im Breisgau, 2019, Ch. 3.1 Cell Culturing, p. 40.
- Presentations** Rapid IVD testing using Planar Waveguide Biosensors. Presented at Biodot Inc. St. Paul Workshop "Emerging Technologies to Enable Quantitative Rapid Tests". 23-25 June 2008. St. Paul Hotel, St. Paul, Minnesota.
- Growing Better Cells for Science. Presented at the Wayne Brown Institute Deal Forum. 15 November 2006. Salt Lake City, Utah.
- ACCS – Advanced Cell Culture System. Presented at HyClone Laboratories Inc. 29 March 2005. Logan, Utah.
- Multiple Vessicle Implantable Drug Delivery Device. Presented to Merck Sharp & Dohme. March 2020. Center for Engineering Design, Salt Lake City, Utah.
- Fluoropolymer-based Electret Materials. Presented to DARPA. July 1988. Center for Engineering Design, Salt Lake City, Utah.
- Awards & Affiliations** Intermountain Society of Inventors and Designers Society of Plastics Engineers
 Intermountain Biomedical Association Utah Soc for Biomaterials Research (President, 1985)
 College of Engineering Scholarship, U of Utah Regent's Scholarship, U of Michigan
 Tau Beta Pi, Engineering Honor Society Phi Kappa Phi, National Honor Society
- After Hours** Inventing | Cooking | Road & Mountain Biking | Alpine & Nordic Skiing | Whitewater Kayaking