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Title: CONSOLE SYSTEM FOR THE TREATMENT OF SKIN

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Patent Trial and Appeal Board
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**DECLARATION OF ERIC SIMON IN SUPPORT OF PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 9,550,052**

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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. 9,550,052 (“The ’052 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 ’052 patent.

2. I have been asked to provide my independent analysis of the ’052 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 ’052 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 ’052 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, 4-12, 15-17 of the '052 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 1-17 of the '052 patent are rendered obvious by Karasiuk, Palmer, and Trueba.
- **Ground 1C:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claim 9 of the '052 patent is rendered obvious by Karasiuk, Palmer, and Mercier.
- **Ground 1D:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 1, 4-12, 15-17 of the '052 patent are rendered obvious by Karasiuk, Palmer, and Wunsch.
- **Ground 1E:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 1-17 of the '052 patent are rendered obvious by Karasiuk, Palmer, Wunsch, and Trueba.

- **Ground 1F:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claim 9 of the '052 patent is rendered obvious by Karasiuk, Palmer, Wunsch, and Mercier.

IV. BACKGROUND KNOWLEDGE PRIOR TO THE PRIORITY DATE OF THE '052 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 '052 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 '052 patent.

Based on instruction from Counsel, I have applied **December 30, 2005** (“Critical

Date”), as the date of the alleged invention of the ’052 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 '052 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. 9,550,052 to Ignon (“the ’052 patent”)
- EUNSUNG-1002 Excerpts from the Prosecution History of the ’052 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. 6,511,486 (“Mercier”)
- EUNSUNG-1018 U.S. Patent Publication No. 2001/0049511 (“Coleman”)
- 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”)
- EUNSUNG-1028 U.S. Patent No. 3,865,352 (“Nelson”)
- EUNSUNG-1029 Nayler, Gordon. Dictionary of mechanical engineering. SAE International, 1996 (“Nayler”)

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. Traditionally, 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 receptacle 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.

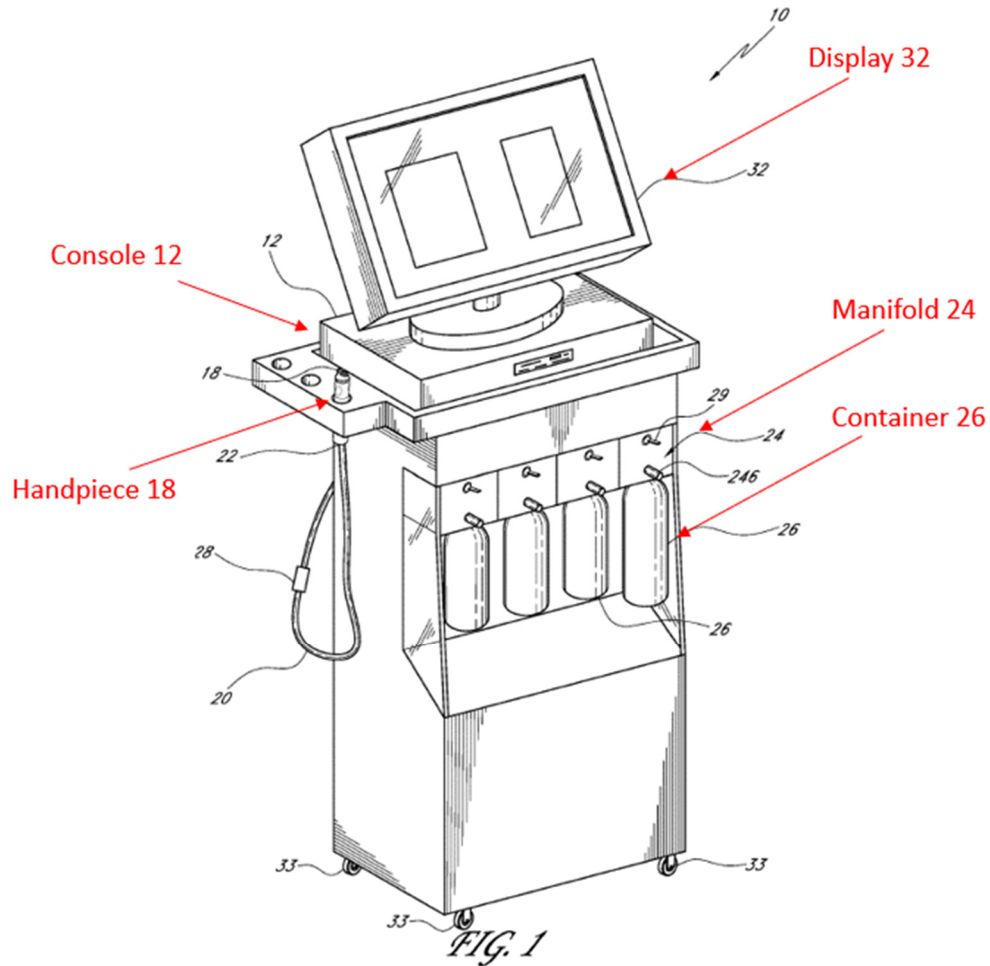
36. In another embodiment, the inert crystals can alternately be replaced by a roughened surface of the tip and known commonly as a diamond microdermabrasion system. EUNSUNG-1026, 1. This type of surface-based system was introduced in the early 2000's. EUNSUNG-1027, Abstract, claim 1.

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 debriding 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 '052 patent

38. The '052 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 '052 patent is representative.

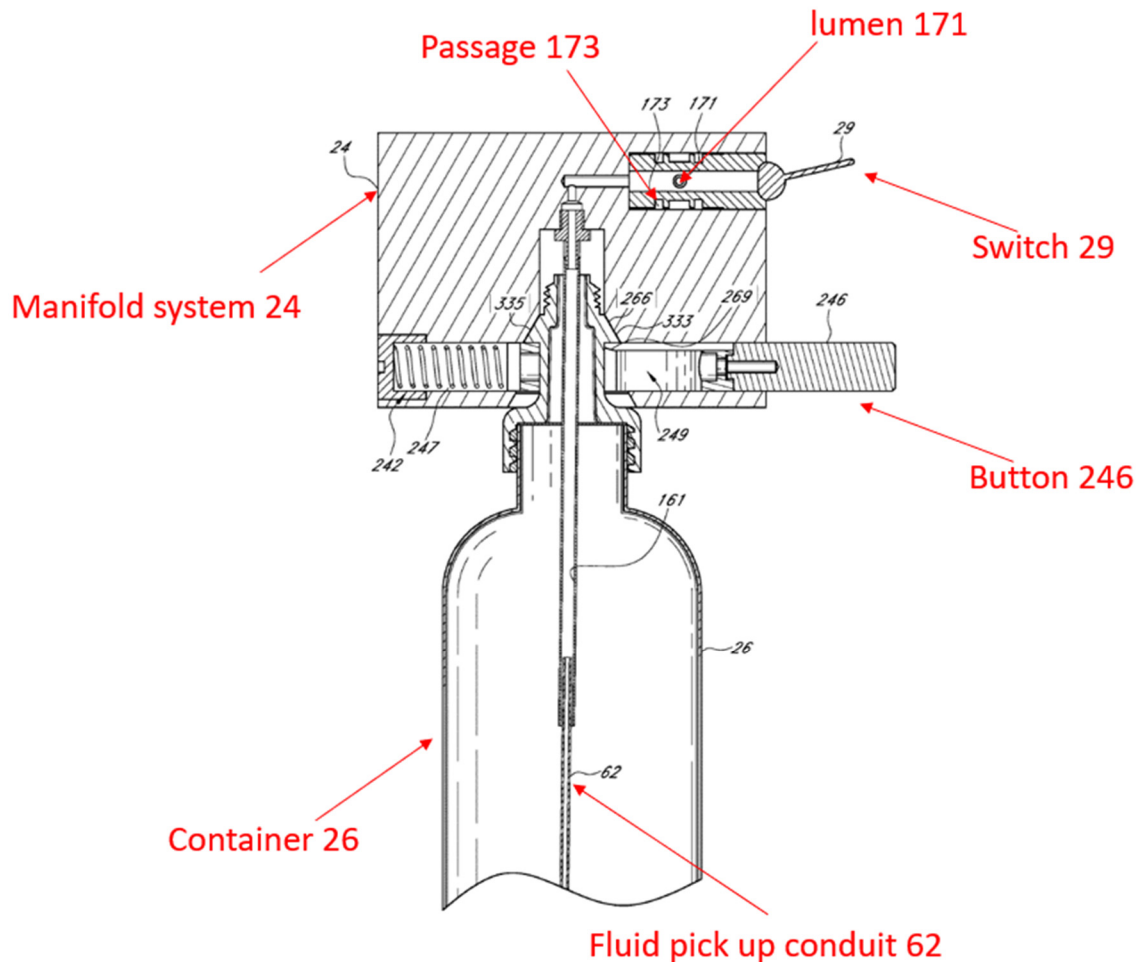


'052 patent, FIG. 1 (annotated)

39. As shown in FIG. 1, the console 12 comprises four casters 33 to allow for easy movement. EUNSUNG-1001, 6:1-3. 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, 6:9-18.

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, 17:5-7. 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, 17:7-17.



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, 17:61-18:6. 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.*

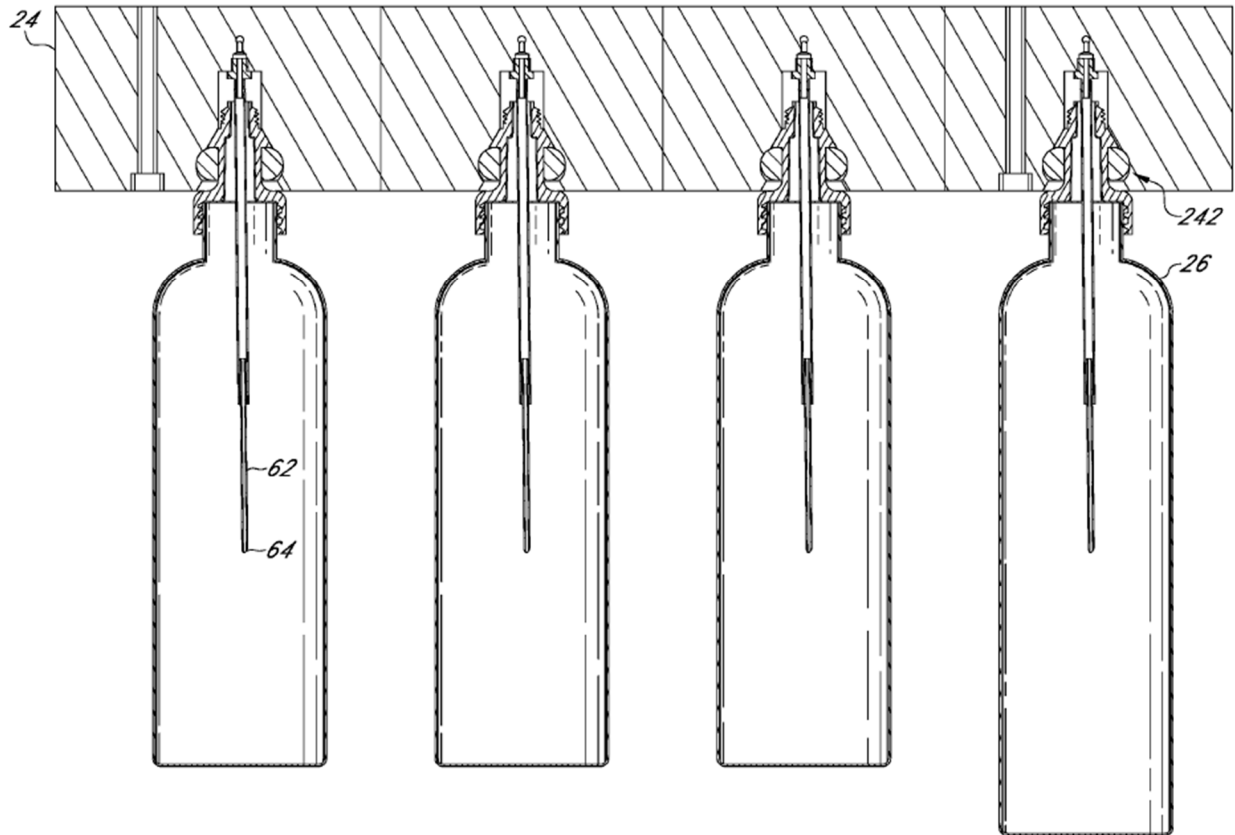


FIG. 15B

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, 5:35-50.

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, 10:58-11:8. The use of positive pressure to actuate fluid flow is not stated in the ‘052 patent.

IX. OVERVIEW OF THE PROSECUTION HISTORY

44. The ‘052 patent was filed on April 28, 2015 as application No. 14/698,673, claiming priority to, among other things, provisional application No. 60/755,310, filed on December 30, 2005. EUNSUNG-1001, Cover.

45. During prosecution, claims 2, 3, 7-9, 11, 12, 14-16, and 20 were rejected as being anticipated by Coleman (US2001/0049511). EUNSUNG-1002, 153-163. Claims 2, 4, 6, 10, 14, 17, and 19 were rejected as being anticipated by Greenberg (US2003/0093089). *Id.* Further, claims 5 and 18 were rejected as obvious over Greenberg and Duchon (US2003/0018252). *Id.* Claims 13 and 21

were rejected as obvious over Coleman and Nelson (US3865352). *Id.*

46. In response, Applicant amended independent claim 2 to recite (1) the manifold being in fluid communication with a first fluid container and at least a second fluid container; (2) a user input device for receiving instructions from a user; and (3) wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly. EUNSUNG-1002, 130-138. Similar amendments were made to independent claim 14. *Id.*

47. In a final rejection, the Examiner rejected claims 4-6 and 17-19 for indefiniteness, and rejected claims 2, 4, 6, 8 to 12, 14 to 17, 19 and 20 as being anticipated by Coleman or in the alternative, as obvious over Coleman in view of Greenberg. EUNSUNG-1002, 98-112. Further, claims 5 and 18 were rejected as obvious over Coleman in view of Greenberg and Duchon. *Id.* Finally, claims 13 and 21 were rejected as obvious over Coleman in view of Nelson or in the alternative, Coleman in view of Greenberg and Nelson. *Id.*

48. In response, Applicant filed a Request for Continued Examination (RCE) and amended independent claim 2 to recite (1) “**wherein the treatment material comprises a liquid**”; (2) a vacuum source; and (3) wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is

created within the waste conduit and along the tip, **thereby removing waste from the skin surface via the waste conduit while drawing treatment material** from the first fluid container or the second fluid container to the tip via the supply conduit. EUNSUNG-1002, 69-79. Similar amendments were made to independent claim 14. *Id.*

49. A Notice of Allowance (NOA) with an examiner's amendment was issued shortly after. EUNSUNG-1002, 31-41. In the NOA, the examiner explained the reasons for allowance:

Claim 2 was amended to recite that **the treatment material comprises a liquid** and that when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, **thereby removing waste from the skin surface via the waste conduit while drawing treatment material** from the first fluid container or the second fluid container to the tip via the supply conduit. These limitations, in combination with the other limitations in the claim are not disclosed or made obvious by the prior art of record.

Specifically, the previously cited Coleman reference fails to disclose or teach that when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit. Instead, Coleman teaches that motor 66 activates valves 62A-62D to draw treatment material from the first fluid container or the second fluid container. Coleman does not disclose or teach that the vacuum source draws treatment material from the fluid containers.

Claim 14 was amended to require a system for performing a skin treatment procedure, the system comprising, inter alia, a manifold in fluid communication with at least two fluid containers, each of the at

least two fluid containers configured to contain a treatment material, wherein **the treatment material comprises a liquid**, a handpiece assembly comprising a tip, a supply conduit secured to the handpiece assembly, a vacuum source, **and a waste conduit in fluid communication with the handpiece and operatively connected to the vacuum source**. Claim 14 further requires that the manifold is configured to control a flow of treatment material from each of the at least two fluid containers through the supply conduit, and that the system is configured to permit a user to select the fluid container from which treatment material is delivered to the supply conduit. These limitations, in combination with the other limitations in the claim, are not disclosed or made obvious in the prior art of record. Claims 16-21 are all dependent on claim 14, and thus are also allowable over the prior art of record. EUNSUNG-1002, 39-40.

50. Thus, the Examiner allowed the claims at least in part because the claims were amended to recite two key limitations: (1) a treatment material that comprises a liquid; and (2) a vacuum source that both removes debris and draws treatment materials. As discussed below, Karasiuk discloses both of these limitations. *See infra* Section X.1.

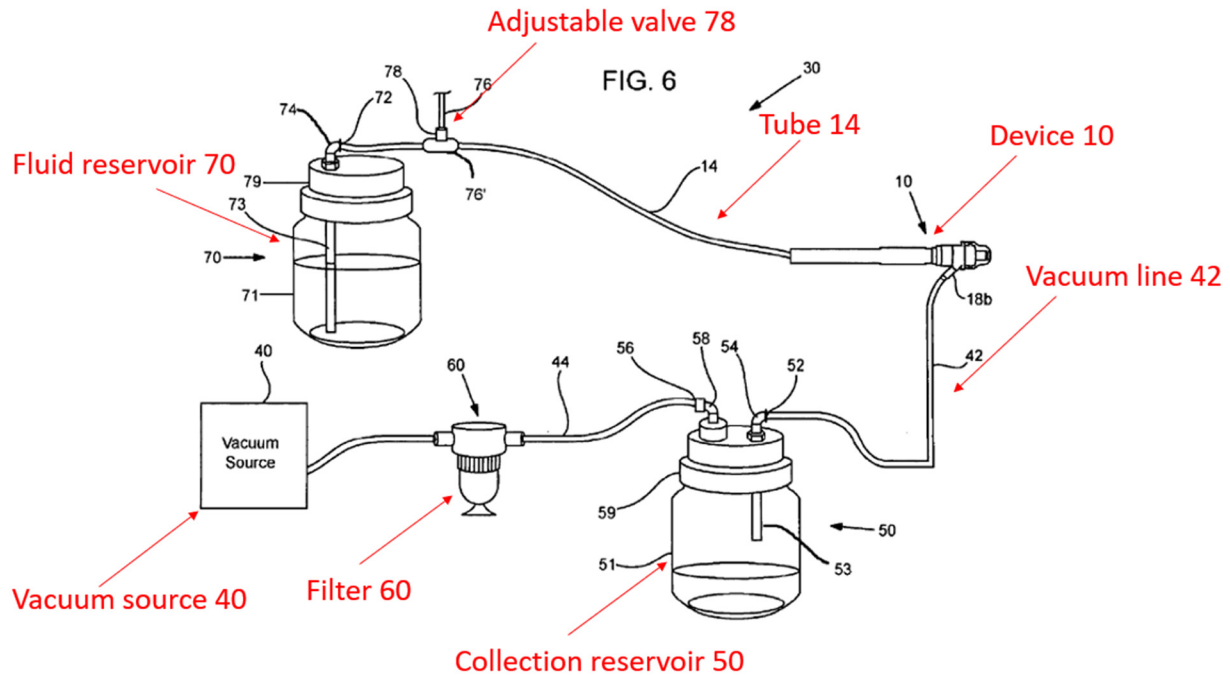
51. During prosecution, the examiner did not consider Palmer, Trueba, or Wunsch. Karasiuk and Mercier were buried in an IDS containing over 300 references. EUNSUNG-1002, 198-213.

X. SUMMARY OF THE PRIOR ART

1. Karasiuk Overview

52. Similar to the '052 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)

53. 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.

54. 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.

55. 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:

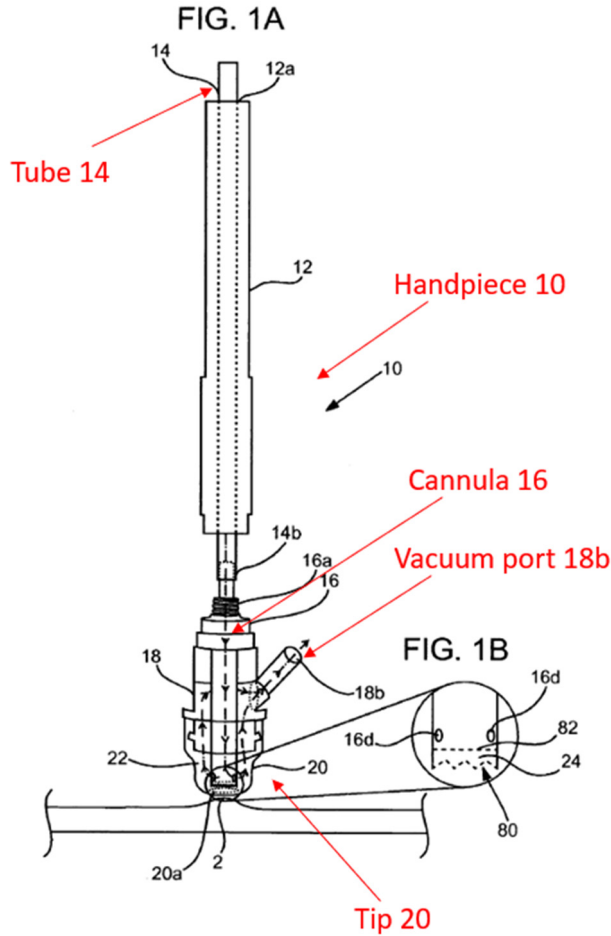
Reservoir 70 may contain solution or a suspension for purposes other than abrasion or pure abrasiveness. General examples, types and/or categories of compounds that may be employed include: beaching formulations (e.g., 2-4% hydroquinone, 2% Kojic Acid, 1% Vitamin K, and 1% Hydrocortisone in a aqueous 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].

56. 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].

57. 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)

58. 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 base 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.

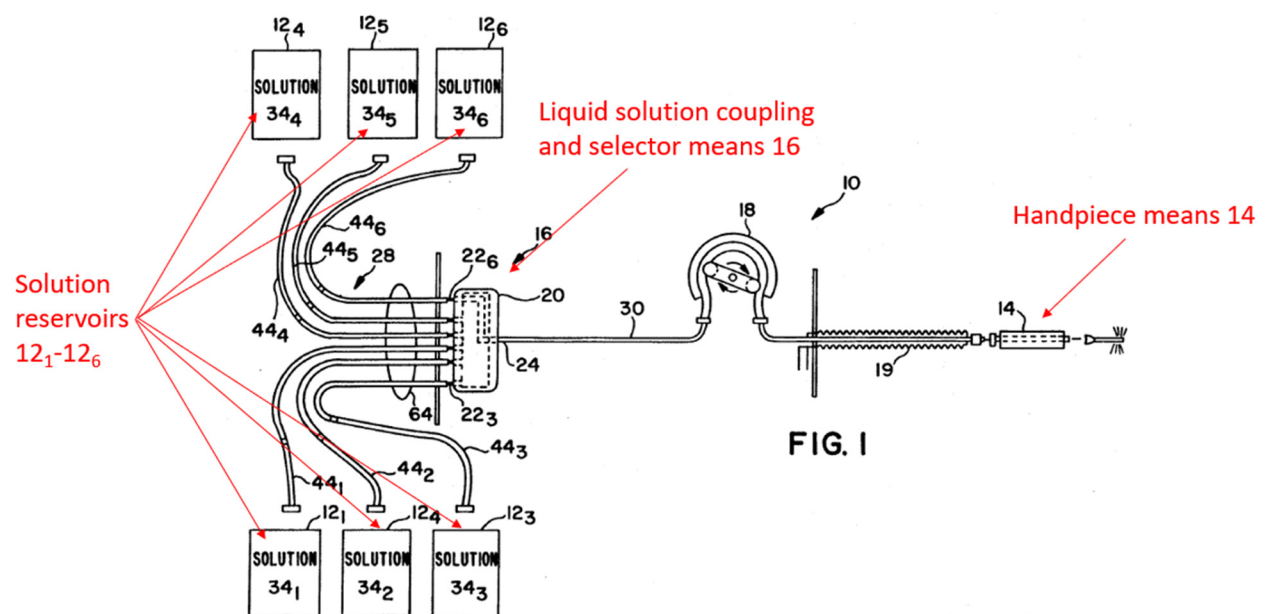
EUNSUNG-1004, [0048]. One or more openings 16d are provided through the wall of the distal tubular structure of cannula 16 to establish one or more flow pathways between passageway 16c and annulus 22. EUNSUNG-1004, [0053].

59. 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

60. Similar to the '052 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.

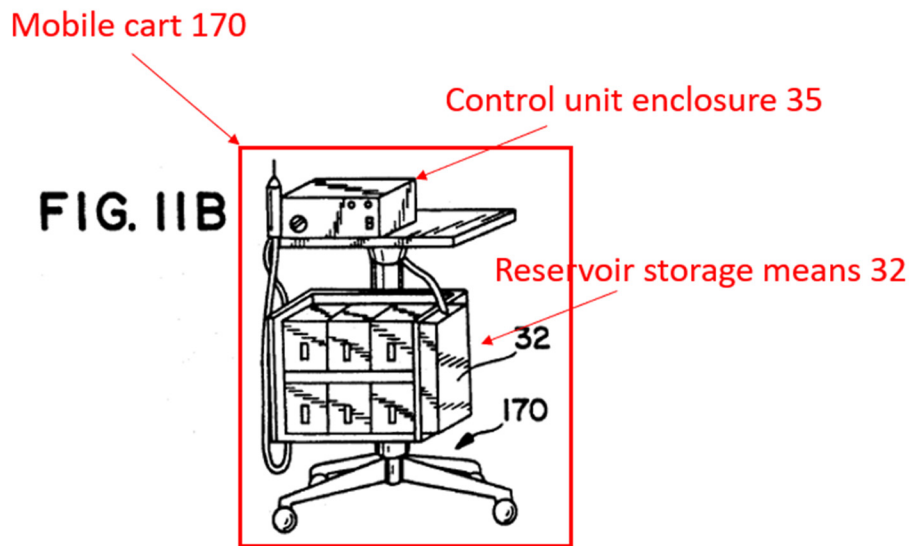


Palmer, FIG. 1 (annotated)

61. 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.

62. Similar to the '052 patent, Palmer also discloses "the reservoir storage means 32 in the form of modular single-shelf racks" for increased portability

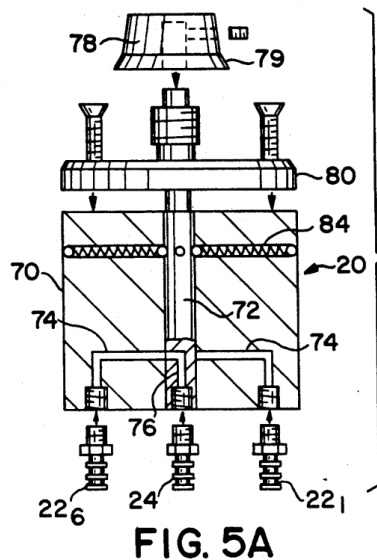
and/or organization. EUNSUNG-1005, 9:58-10:16 (“a high degree of flexibility”), FIGS. 11A (“countertop 168”), 11B (“mobile cart 170”), 11C (“cabinet 172 underneath a counter”); As shown in FIG. 11B below, for example, Palmer’s “mobile cart 170” includes the control unit enclosure 35 and the reservoir storage means 32.



Palmer, FIG. 11B (annotated)

63. 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. A liquid outlet passage 76 is formed in the rotatable core 72”. EUNSUNG-1005, 8:6-14. Selector valve means 20 is directly analogous

to the manifold system (aka, “block” in the claims) of the ‘052 patent, having fluidic input and output, valving, switching, and manifolding functionalities. The cylindrical exterior form of the valve means 20 does not impact these functionalities and thus is non-limiting; indeed, the exterior form of valve means 20 would comprise a more block-like rectilinear geometry and the component would function the same. Moreover, the exterior form of the manifold system (aka, block) is not limited to any disclosure of the ‘052 patent. Both manually-switched rotary fluidic valves (Palmer) and fluidic block manifold structures (the ‘052 patent) were well known fluidics components by the Critical Date.

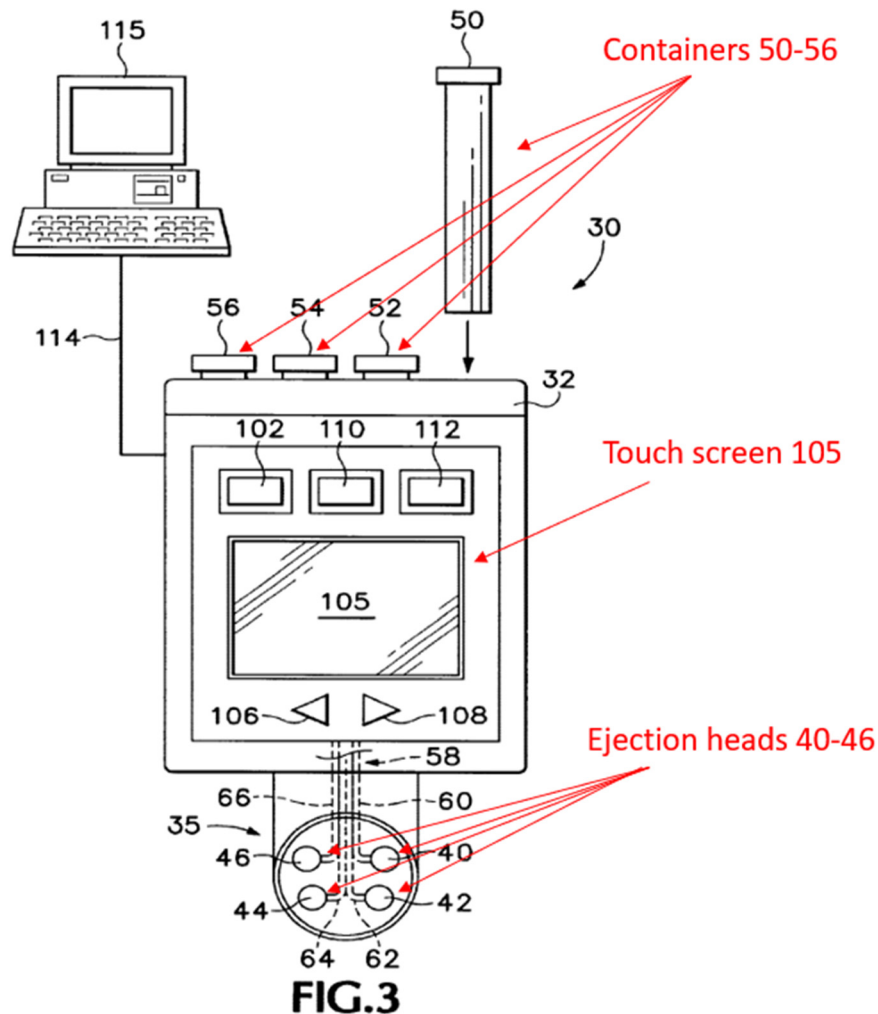


Palmer, FIG. 5A

3. Trueba Overview

64. 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)

65. 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.

66. 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.

67. 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”).

68. Further, the device can be programmed to respond to changing clinical circumstances. EUNSUNG-1008, 11:15-20 (“For example, only the

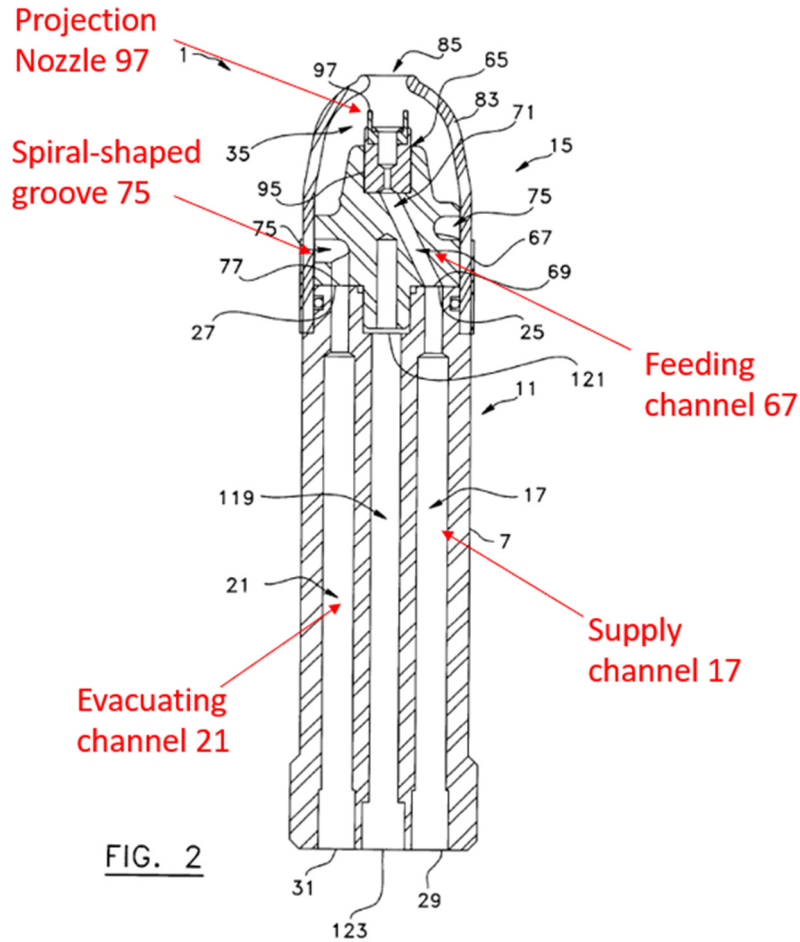
corticosteroid from reservoir 52 would be administered to a subject having stable reactive airway disease. However, if symptoms persist, then the β -agonist from reservoir 50 also can be delivered.”). Further, the device can be programmed to “prevent unauthorized alteration of dosages” and “permit certain ranges of dosages to be administered.” EUNSUNG-1008, 12:2-9.

4. Mercier

69. Similar to Karasiuk, Mercier discloses a dermabrasion device for abrasively removing skin surface. EUNSUNG-1017, Title and Abstract. Mercier’s device “has a projection head for projecting the abrasive stream **orthogonally** to the skin surface to be removed; an evacuation chamber operatively connected to the evacuating channel for facilitating evacuation of the removed skin surface and used abrasive stream into the evacuating channel; and **rotation-inducing mechanisms** for giving a rotational pattern to the abrasive stream projected from the operative head.” EUNSUNG-1017, Abstract.

70. Mercier discloses that its handpiece design with the “rotation-inducing mechanisms” is advantageous because it allows “great stability of the projected abrasive stream” and “creates a homogeneous sweeping action in the manner of a generally rotational rubbing motion,” which enables the device to project an abrasive stream orthogonally to the skin surface to be removed without causing “skin stabbing” thereon. EUNSUNG-1017, 2:11-14 and 11:61-12:15.

71. Specifically, Mercier's feeding channel 67 can include one coaxial groove 107 so as to induce the rotational pattern onto the abrasive stream 5 projected through the feeding channel 67. EUNSUNG-1017, 8:22-28. Further, Mercier's projection nozzle 97 can include a projection channel 101 with one coaxial groove 109 so as to induce the rotational pattern to the abrasive stream 5 projected through the projection channel 101. EUNSUNG-1017, 8:28-33. As shown in Mercier's FIG. 2, Mercier's handpiece includes (1) a supply channel 17 for delivering treatment solution to the operative head 15 from a supply stream source 19 and (2) an evacuating channel 21 for removing debris to an evacuating means 23. EUNSUNG-1017, 4:56-61.



Mercier, FIG. 2

72. As shown in FIG. 6 below, the projection head 33 comprises a spiral-shaped groove 75 which cooperates with the evacuation chamber 35 to evacuate the removed skin surface 3 and used abrasive stream 5 from the evacuation chamber 35 into the evacuating channel 21. EUNSUNG-1017, 6:37-55, FIG. 6.

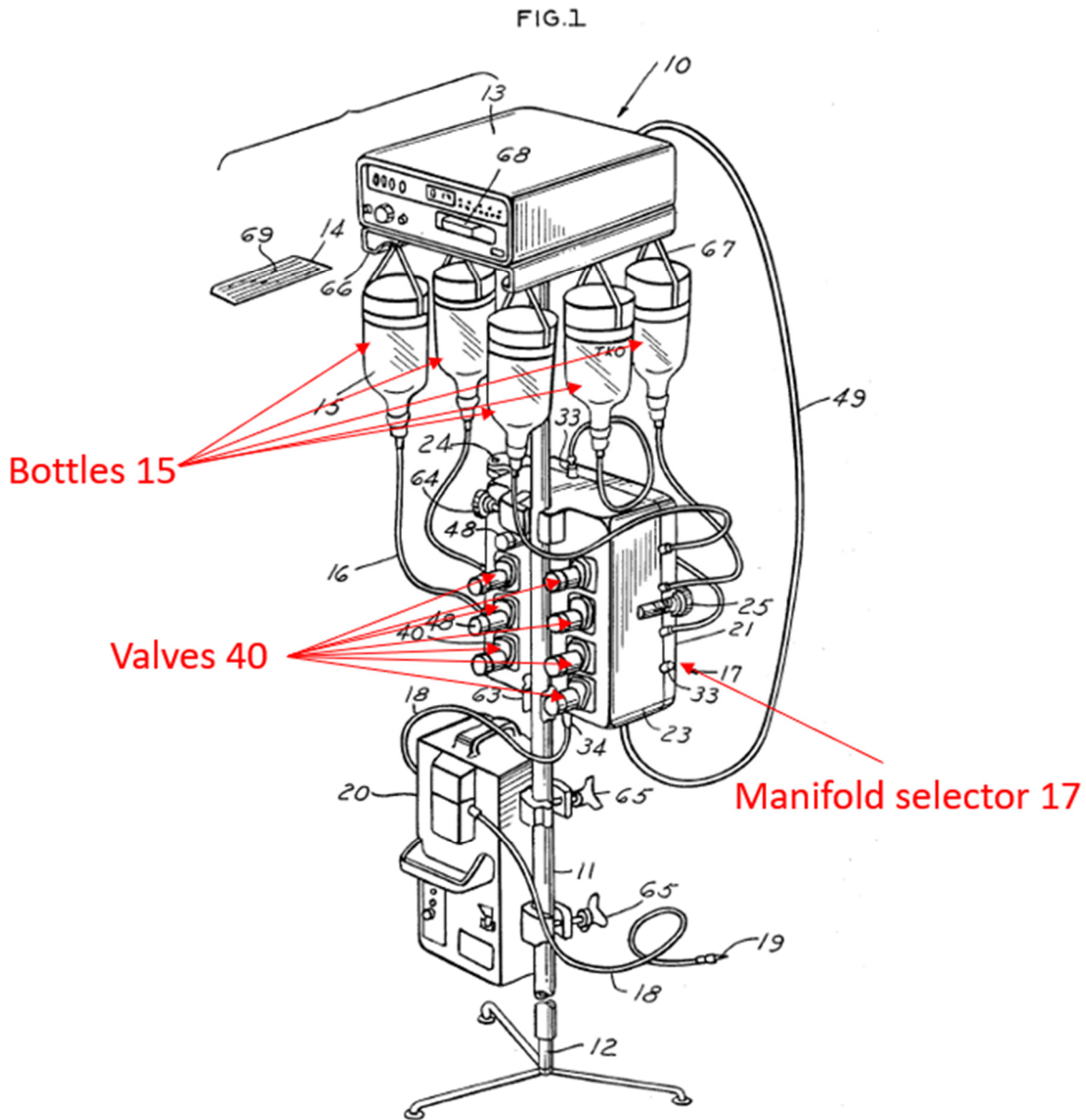


Mercier, FIG. 6

5. Wunsch

73. Wunsch discloses an apparatus 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. Each of the valves 40 has an open position in which fluid is permitted to

flow from the supply tubes 16 into the dispensing tube 18 and a closed position in which the branch tube 37 or trunk 32 is pinched off to prevent fluid flow therethrough. EUNSUNG-1020, 7:52-56.



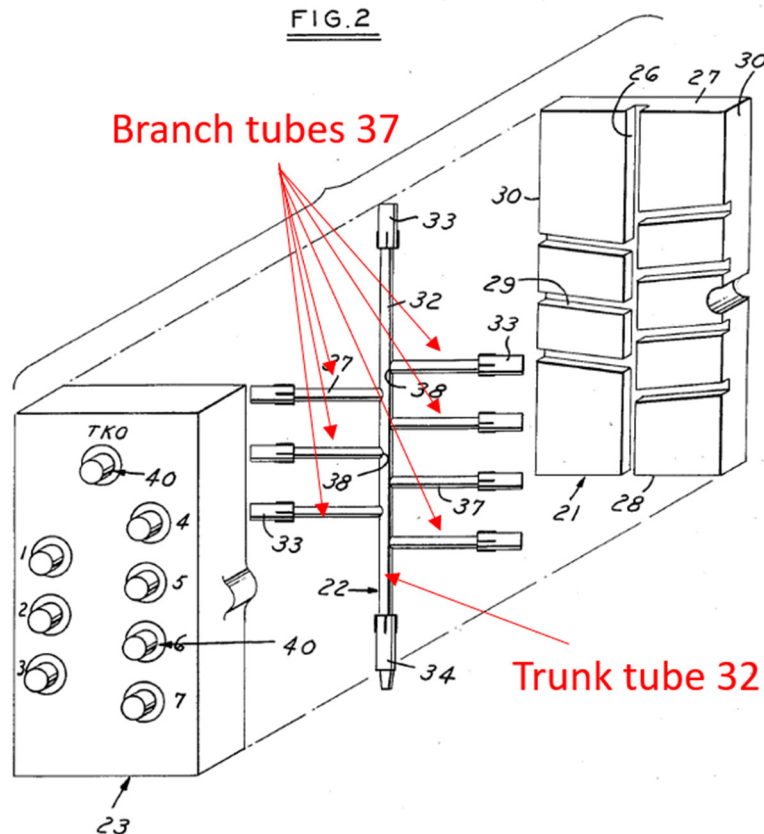
Wunsch, FIG. 1 (annotated)

74. Wunsch further discloses exemplary reversible electric motors 48,

FIG. 3, or solenoids 59, FIG. 4, for individually controlling the operation of the respective valves 40. EUNSUNG-1020, 3:16-22, 6:24-26, FIGS. 3-4. These motors are connected to and controlled by a sequencer-timer 13. EUNSUNG-1020, 5:25-35, 8:27-9:5. 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.

75. As shown below in FIG. 2, Wunsch's manifold selector 17 includes a manifold 22 including a trunk tube 32 and a plurality of branch tubes 37, each of which connecting to one of the plurality of bottles 15. EUNSUNG-1020, 3:23-42, 6:61-7:16. In operation, by activating an individual valve 40, the user can selectively connect a chosen bottle 15 to the trunk tube 32 for delivery.

EUNSUNG-1020, 3:23-42 ("Upon operation of an electric motor means, such as a reversible motor, or a solenoid is adapted to retract the valve element of the valve for a predetermined period to permit the passage of intravenous fluid in one of the branches or through the inlet of the manifold for a predetermined period."), 7:17-56.

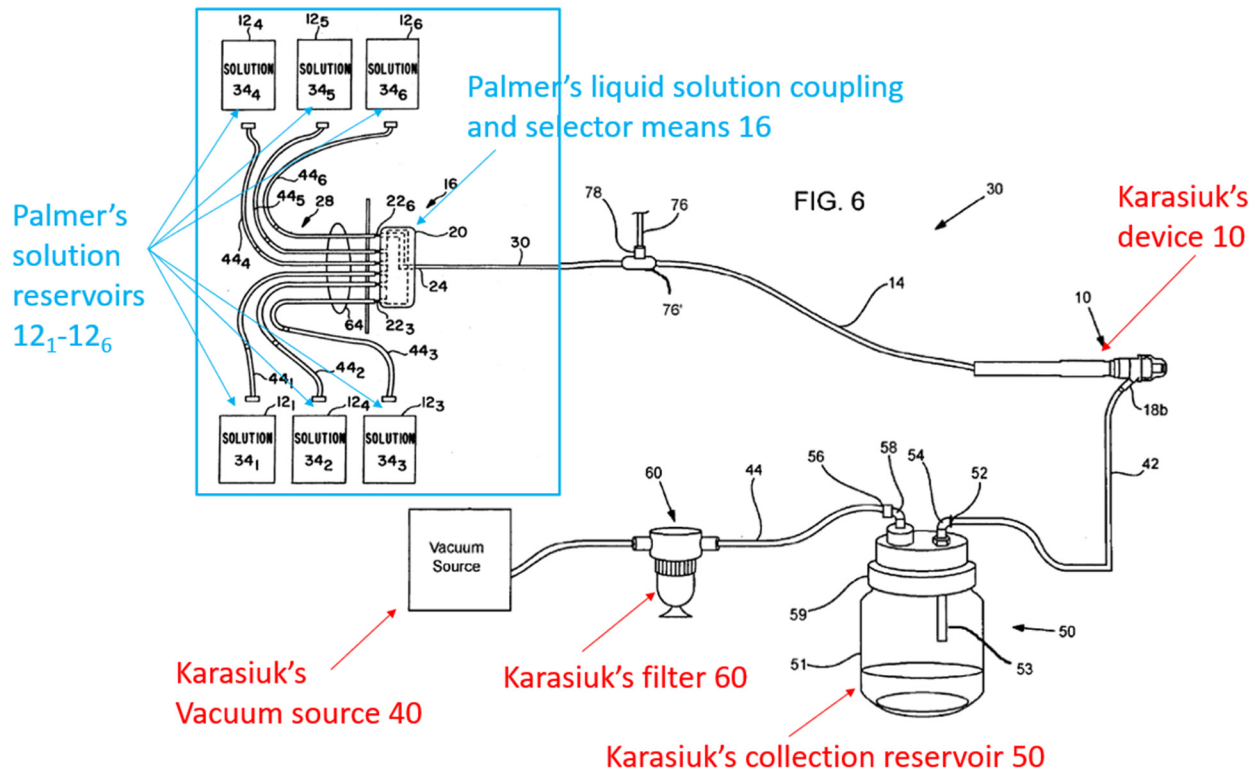


Wunsch, FIG. 2 (annotated)

XI. [GROUND 1A]: Karasiuk-Palmer

1. Karasiuk-Palmer Combination

76. 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)

77. 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].

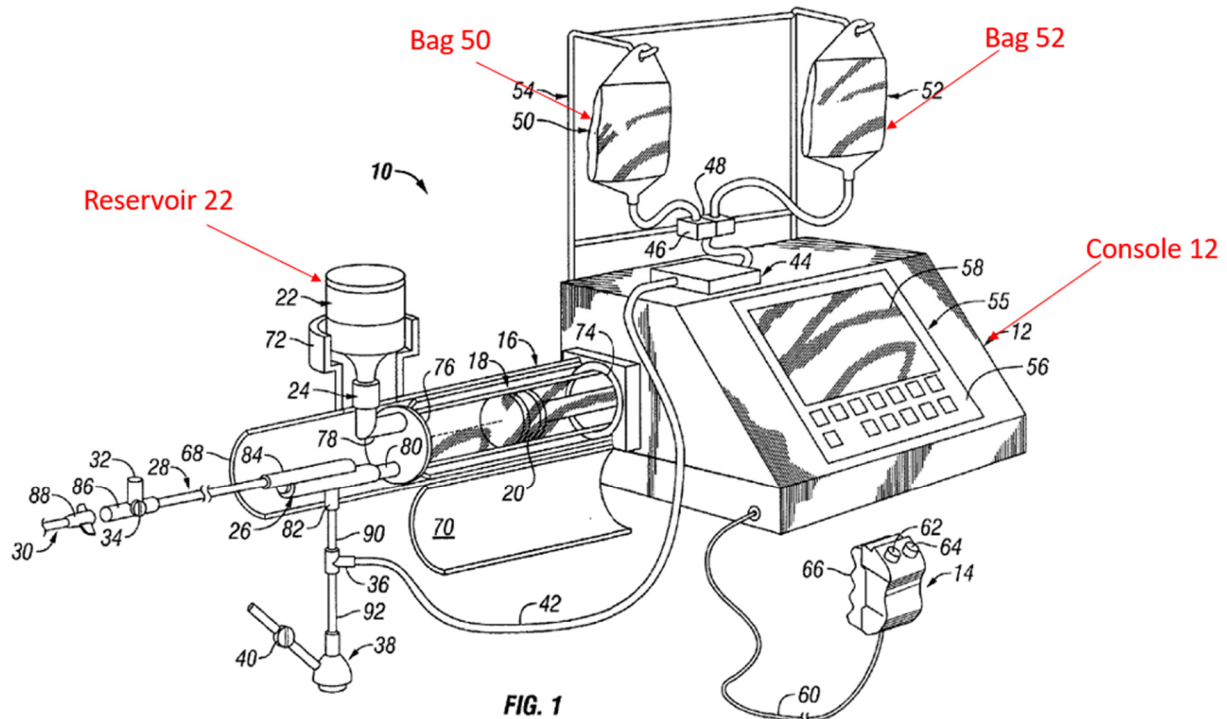
78. In addition to adapting Karasiuk's system to use multiple treatment containers in the Karasiuk-Palmer combination, a POSITA would have been motivated and found it obvious to place both (1) multiple containers and selector means (e.g., Palmer) and (2) handpiece, waste container, filter, and vacuum 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.

79. 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.

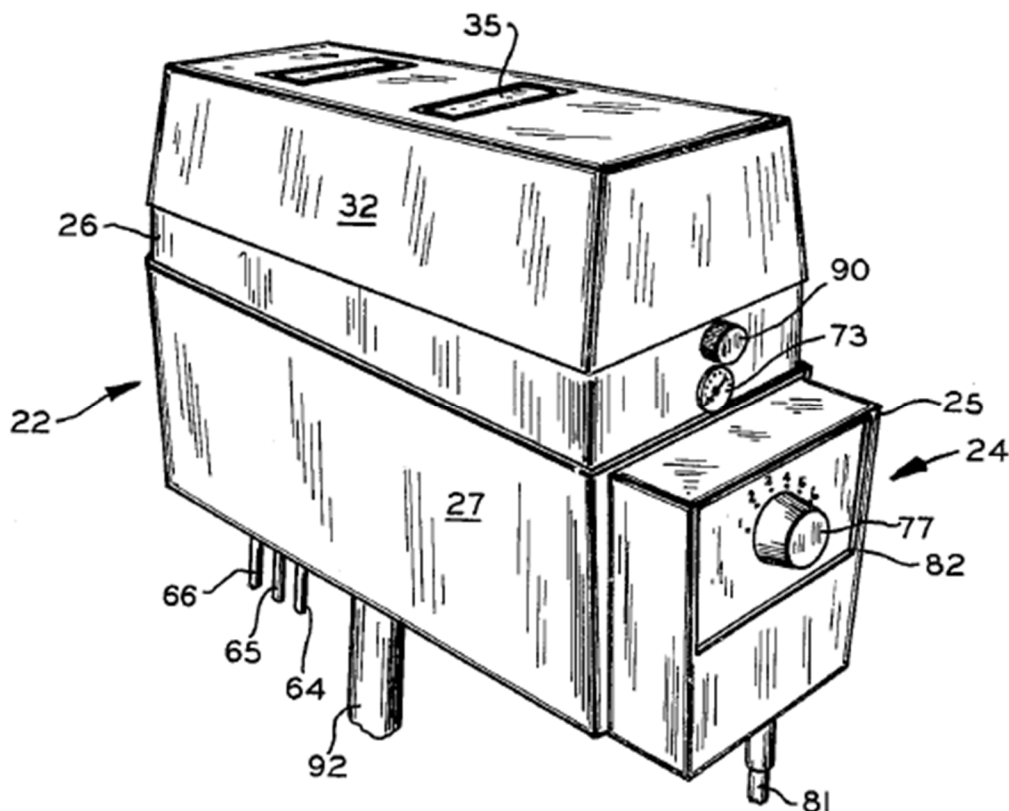
EUNSUNG-1010, [0063].



Duchon, FIG. 1 (annotated)

80. 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

81. 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.

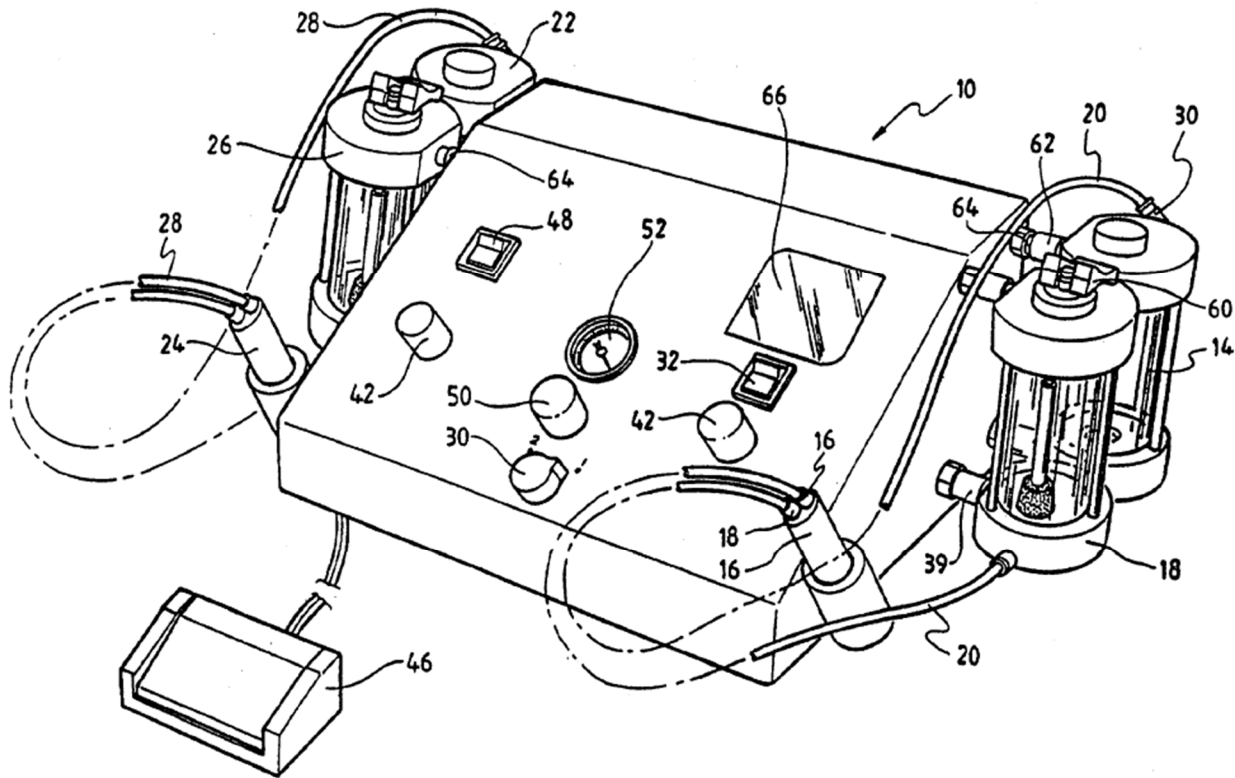
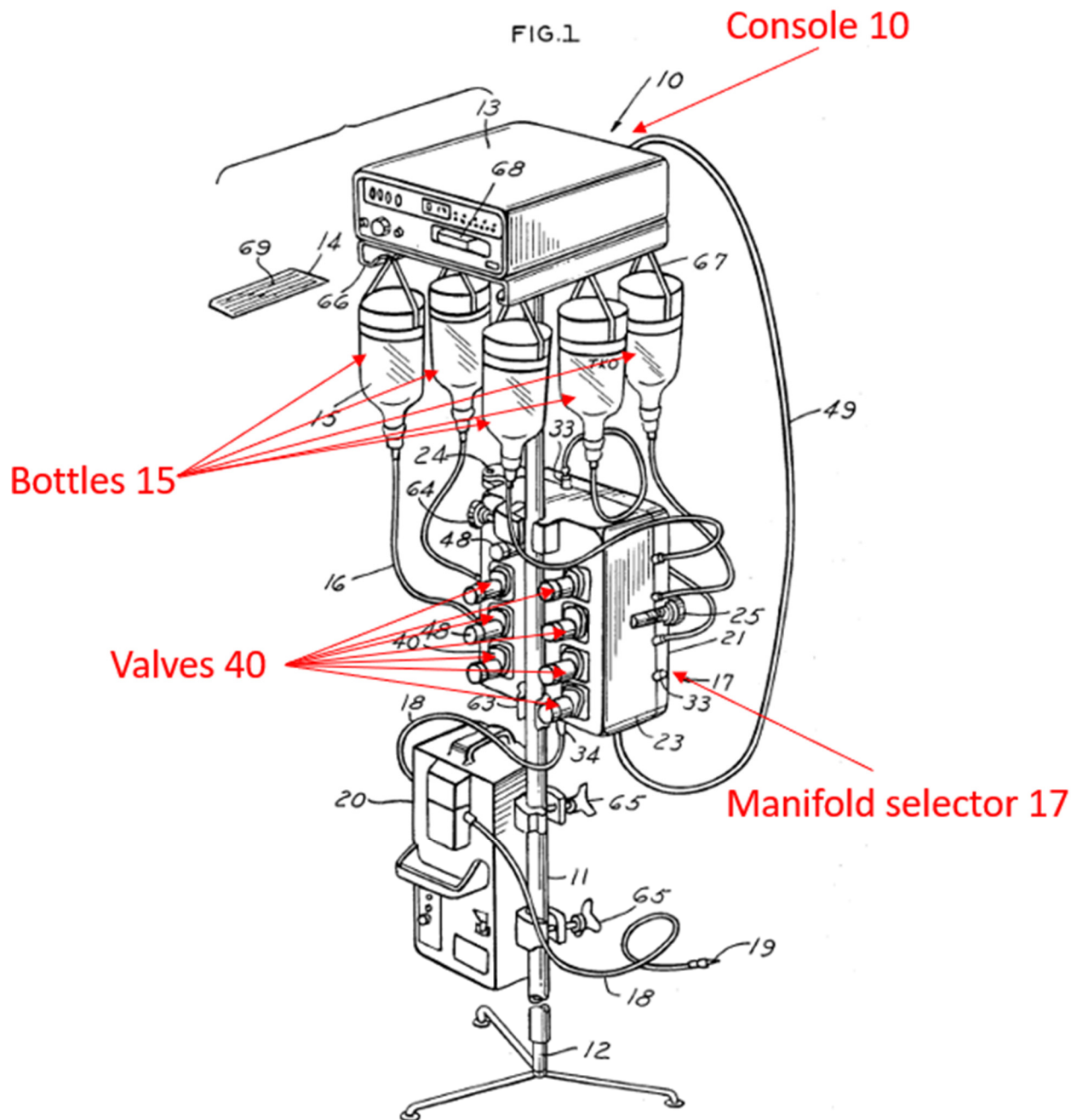


FIG 1

Greenberg, FIG. 1

82. 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)

83. Several reasons would have prompted a POSITA to modify Karasiuk's system based on Palmer's teachings. As discussed in Section 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); alphilipoic acid (antioxidant); benzoil 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.

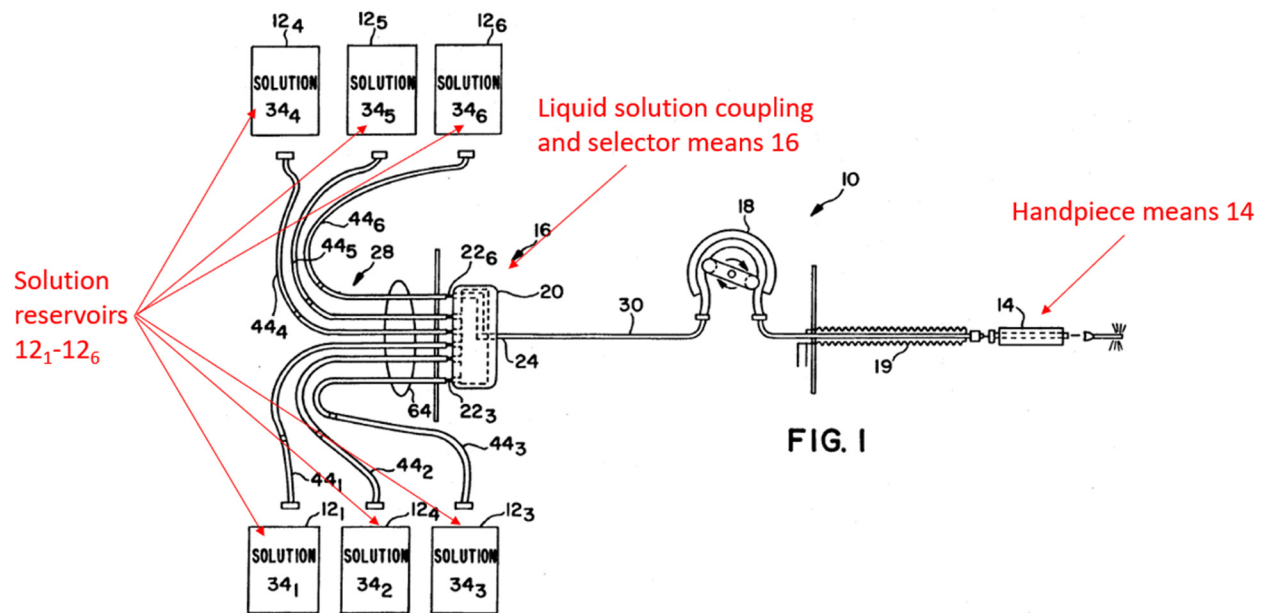
EUNSUNG-1004, [0061].

84. 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.

85. 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

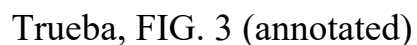
well-known and part of a POSITA's general knowledge by the Critical Date.

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.

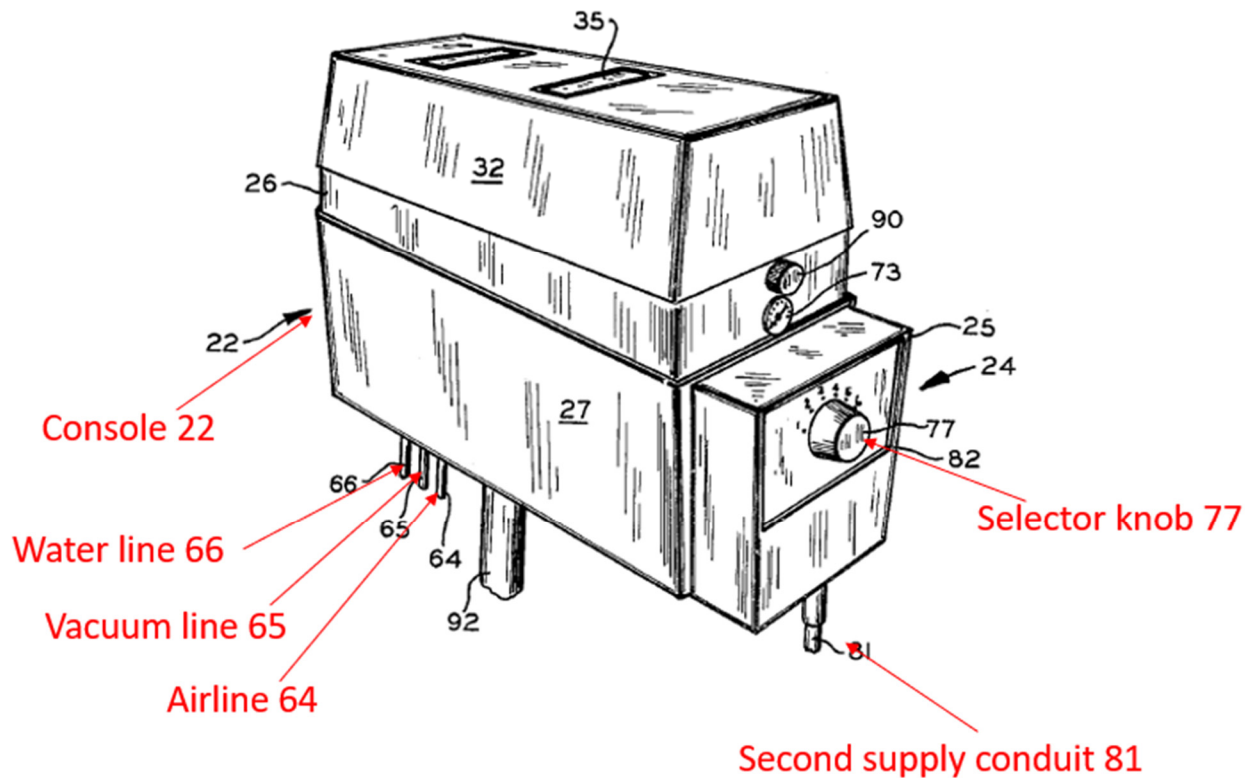


Palmer, FIG. 1 (annotated)

86. 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



87. 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)

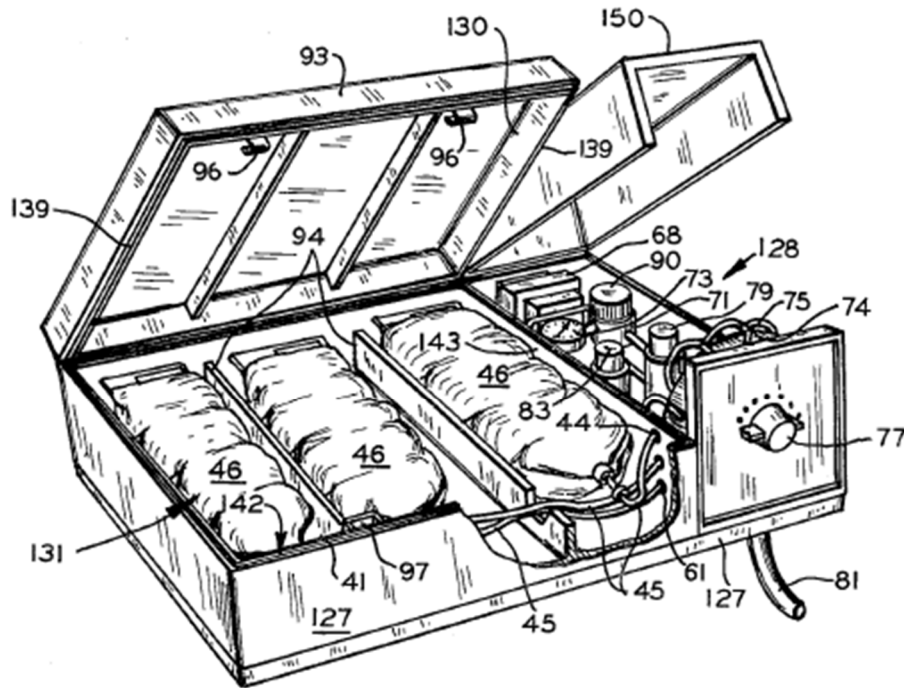
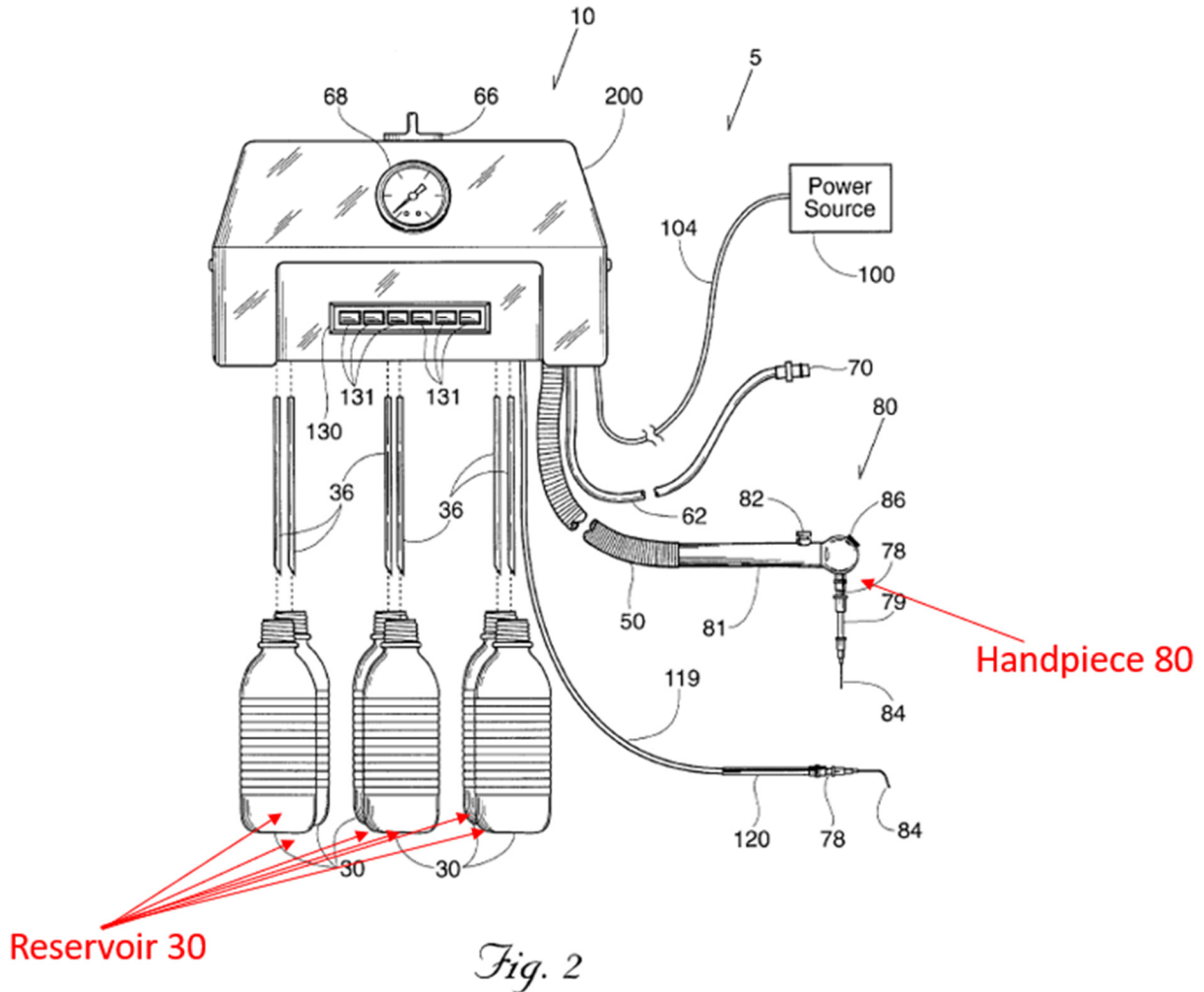


FIG. 7

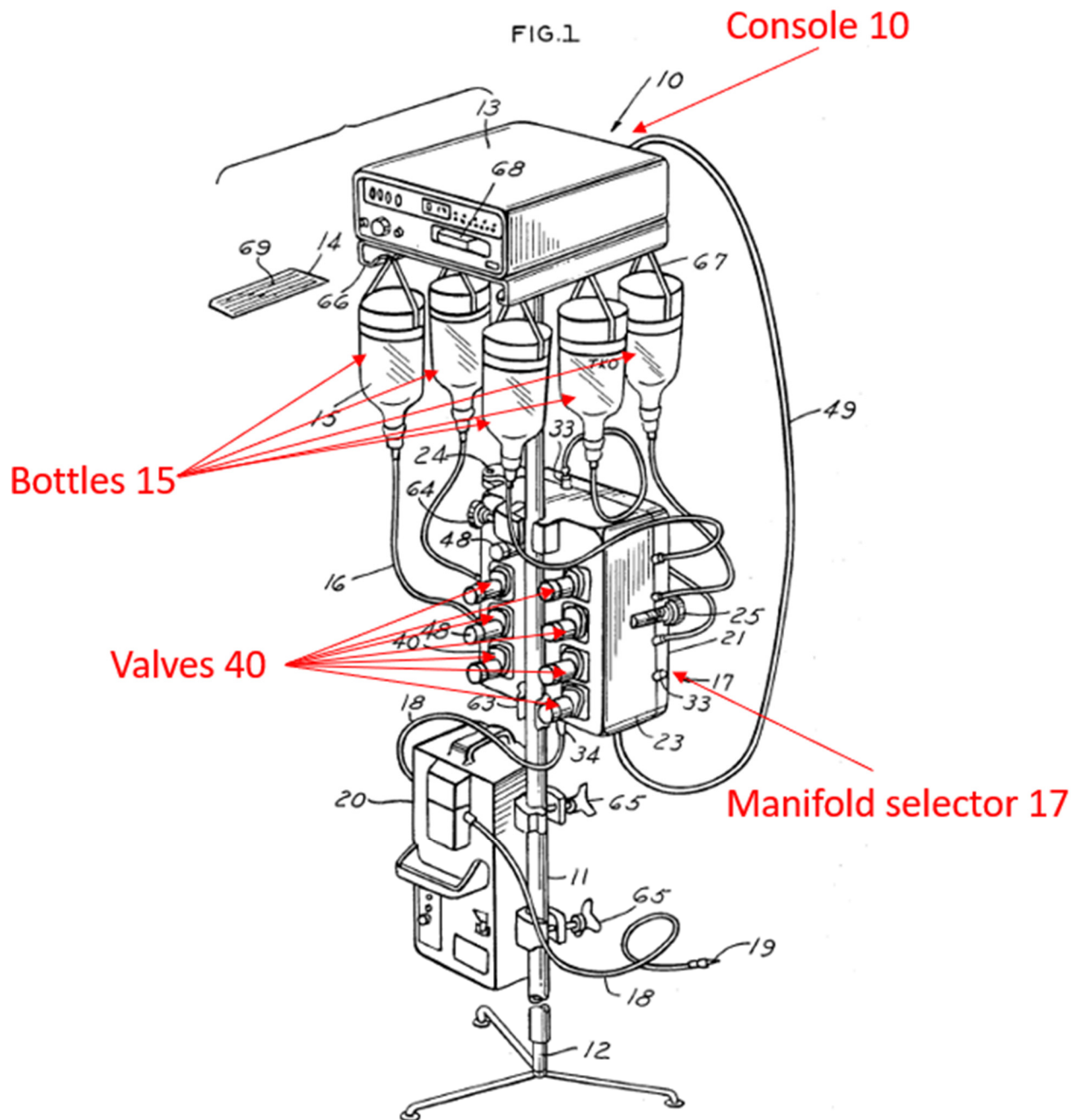
Armstrong, FIG. 7

88. 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)

89. 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.



Wunsch, FIG. 1 (annotated)

90. 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.

91. 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.

92. 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.

93. 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.

94. 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, 6:41-44. 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.

95. 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

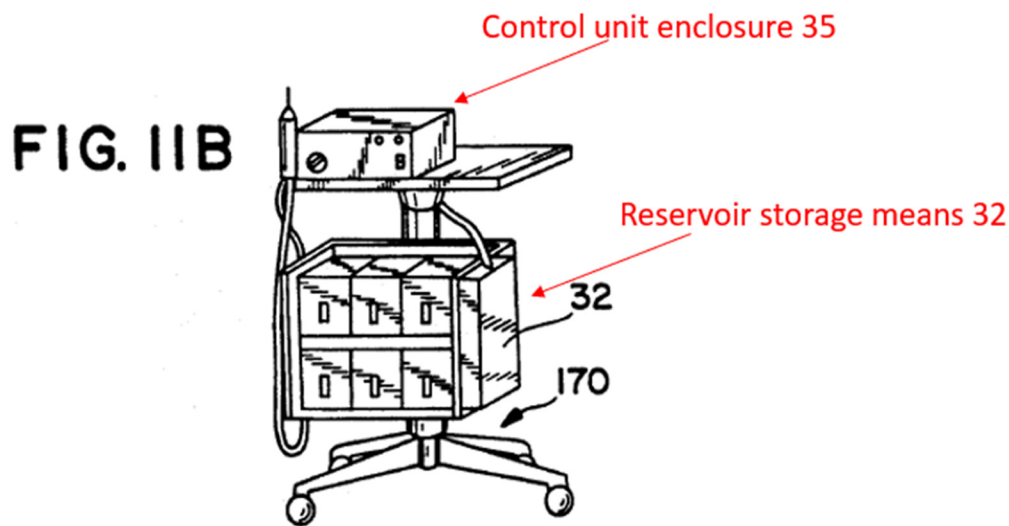
[1.pre] A system for performing a skin treatment procedure, the system comprising:

96. It is my opinion that Karasiuk-Palmer renders obvious a system (e.g., Karasiuk’s microdermabrasion system 30) for performing a skin treatment procedure (e.g., microdermabrasion). 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 including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;

97. It is my opinion that Karasiuk-Palmer renders obvious a console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid. The Karasiuk-Palmer system includes a *console* in the form of, for example, “mobile

cart 170” that receives Palmer’s multiple containers (reservoir storage means 32 receiving multiple reservoirs) and selector means (control unit enclosure 35), and also receives Karasiuk’s handheld device 10, collection reservoir 50, vacuum source 40, and other relevant components in a modular structure. Section XI.1; EUNSUNG-1005, 9:58-10:2, FIGS. 11A-11C.



Palmer, FIG. 11B

98. This aligns with the '052 patent’s disclosure of console that receives multiple containers, valve system, handpiece, vacuum pump, and waste container, and is placed on four casters for “easy movement.” EUNSUNG-1001, 14:26-36, 9:6-8, 18:27-34, 10:59-60, 5:61-6:3, 7:35-37.

99. Alternatively or additionally, a POSITA would have been motivated and found it obvious to place Karasiuk-Palmer’s system (including Palmer’s multiple containers) in a console for known benefits, such as increased portability

and organization. Indeed, using a console to house similar medical devices were well-known and would have been within a POSITA's general knowledge.

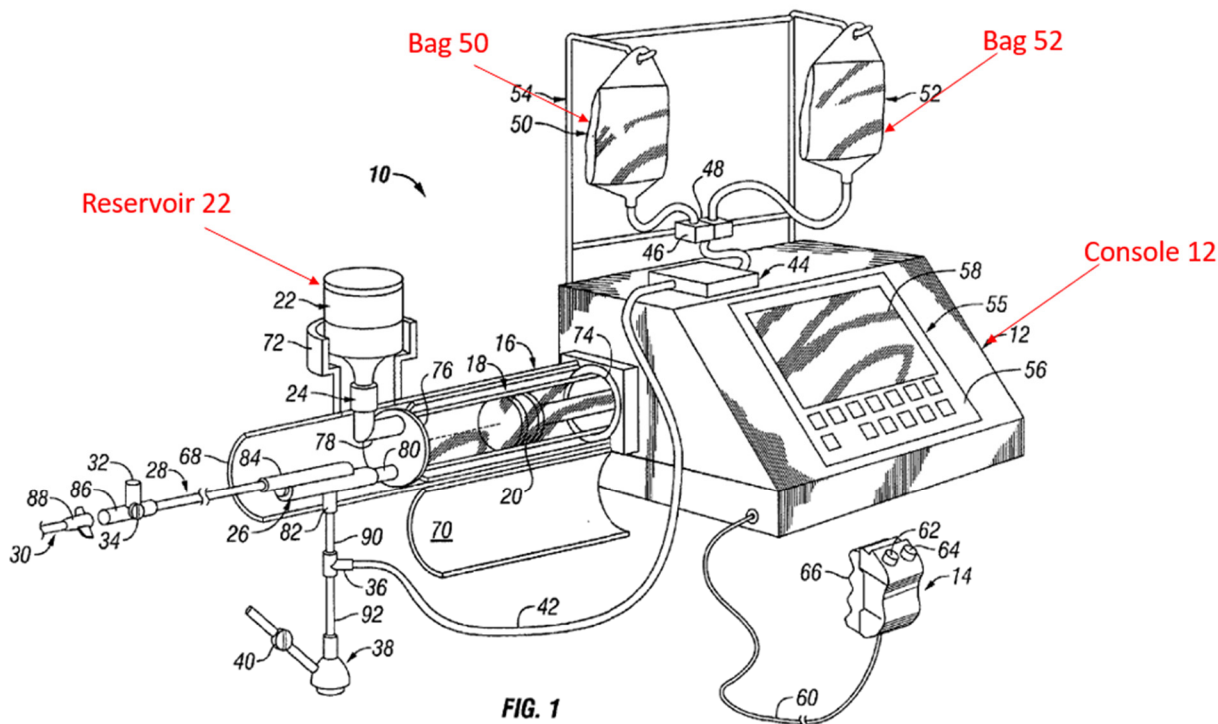
EUNSUNG-1010, FIGS. 2A-2G, 7A-7D, [0063] ("Console 12 houses the electrical controls for system 10, together with the motors which drive piston 20 and peristaltic pump 44."), [0088], [0154] ("The console and power supply are mounted to a cart, generally indicated at 402 which includes wheels for easy 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.

100. 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

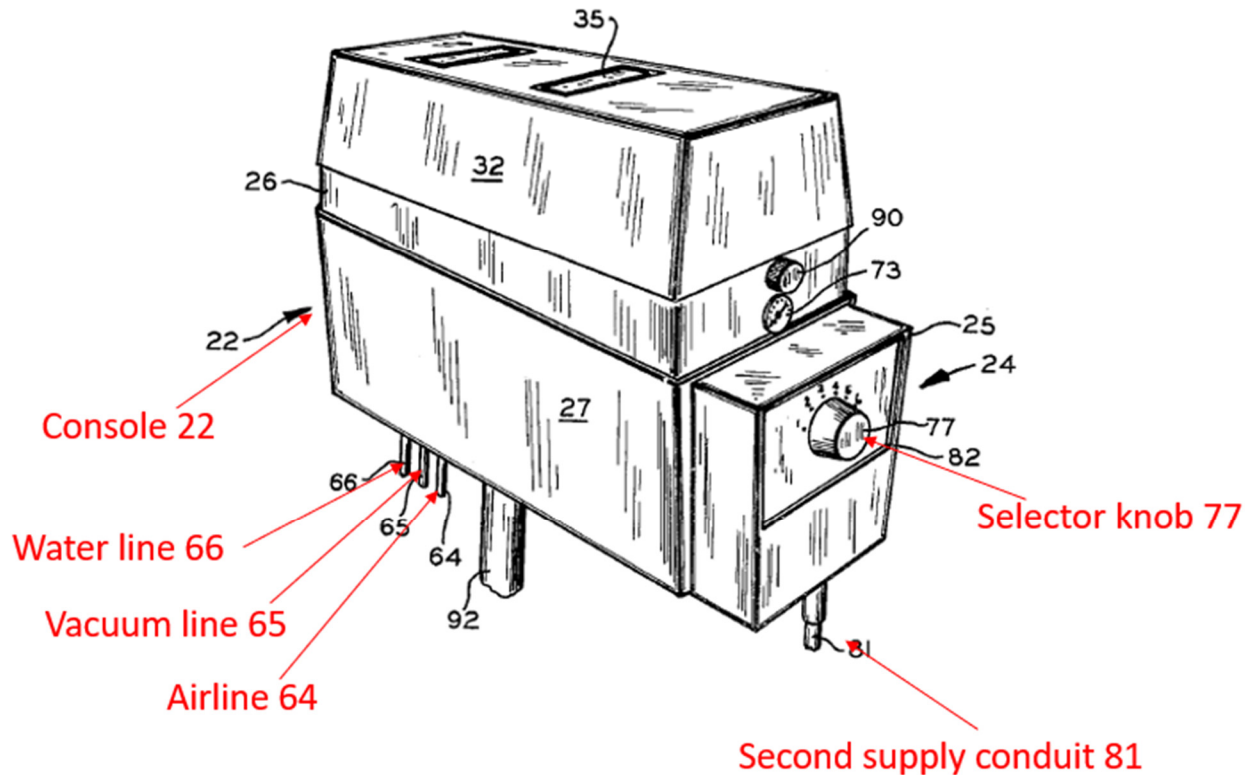
pump 44. On the front surface of **console 12**, user interface 55 provides control switches 56 and display 58 through which the user may enter control settings and monitor the operational state of system 10. The console can be free-standing, preferably configured for mounting on a transport cart assembly.

EUNSUNG-1010, [0063].



Duchon, FIG. 1 (annotated)

101. 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.

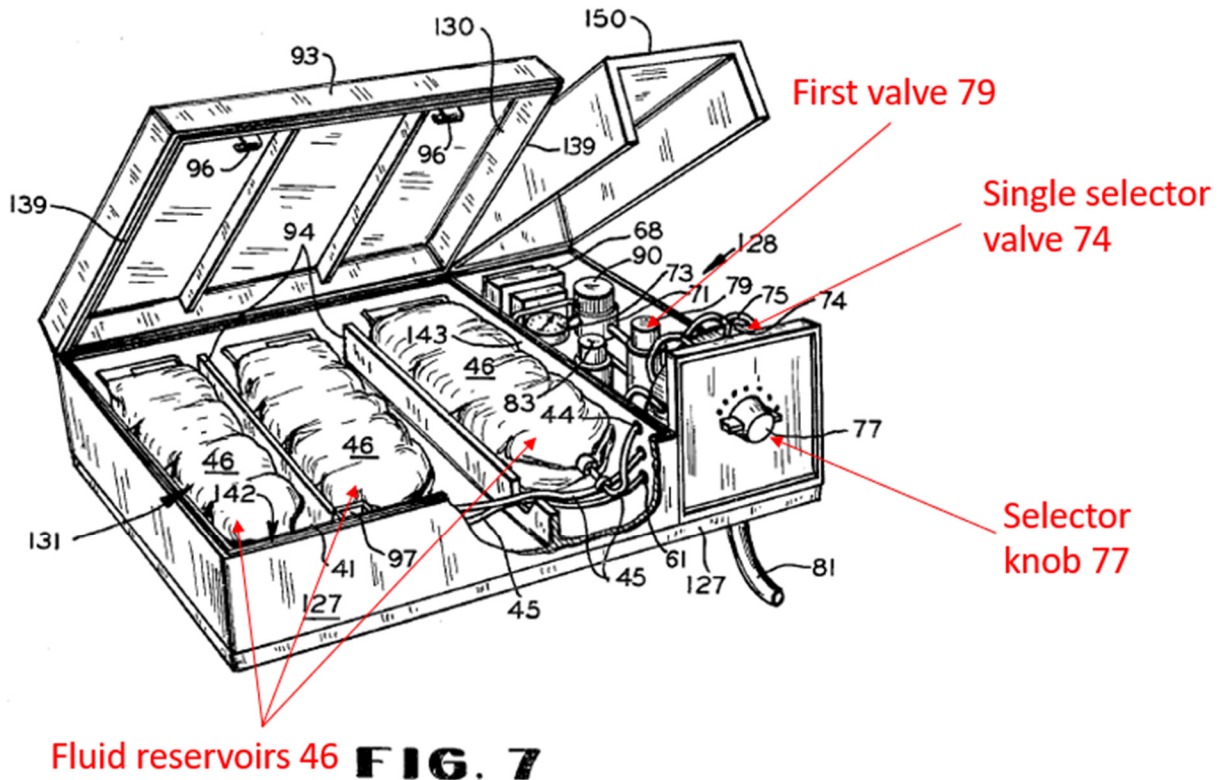


Armstrong, FIG. 2 (annotated)

102. Armstrong discloses in relevant part:

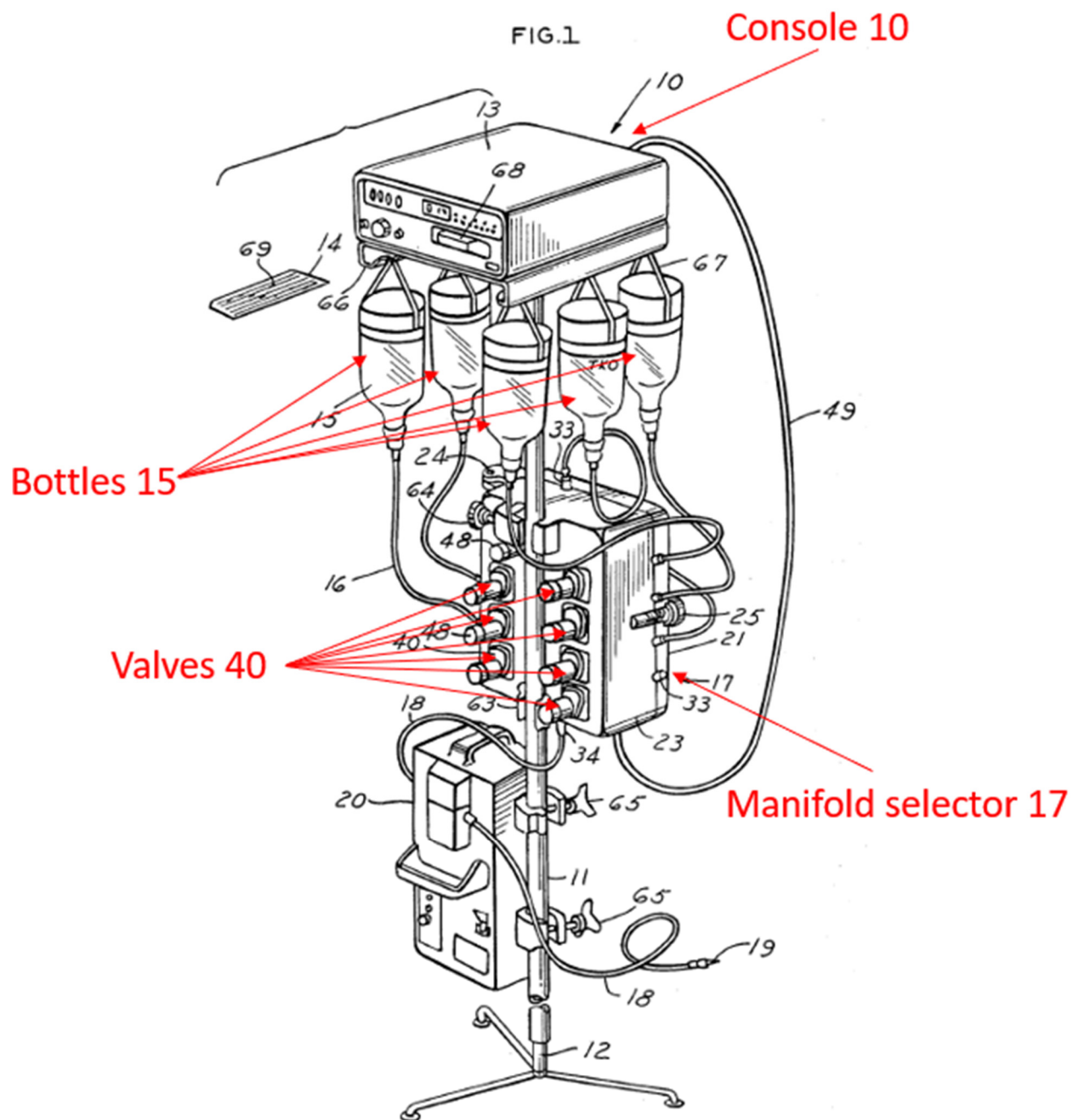
FIG. 2 shows the system 21 of FIG. 1 with the control box 82 secured to the supply station 22. In this embodiment the supply station 22 is supported by a pedestal 92 so that, if desired, the entire system 21 may be placed next to the patient treatment area. This embodiment is typically used in a dental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



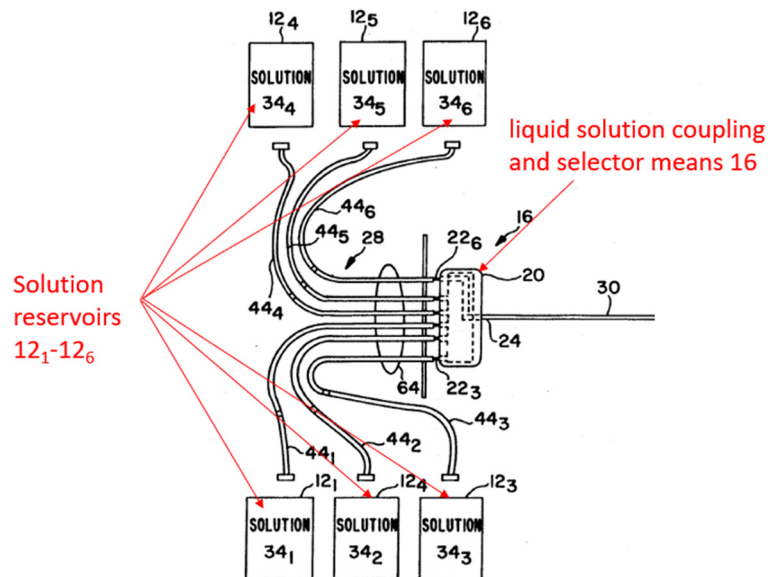
Armstrong, FIG. 7

103. 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.



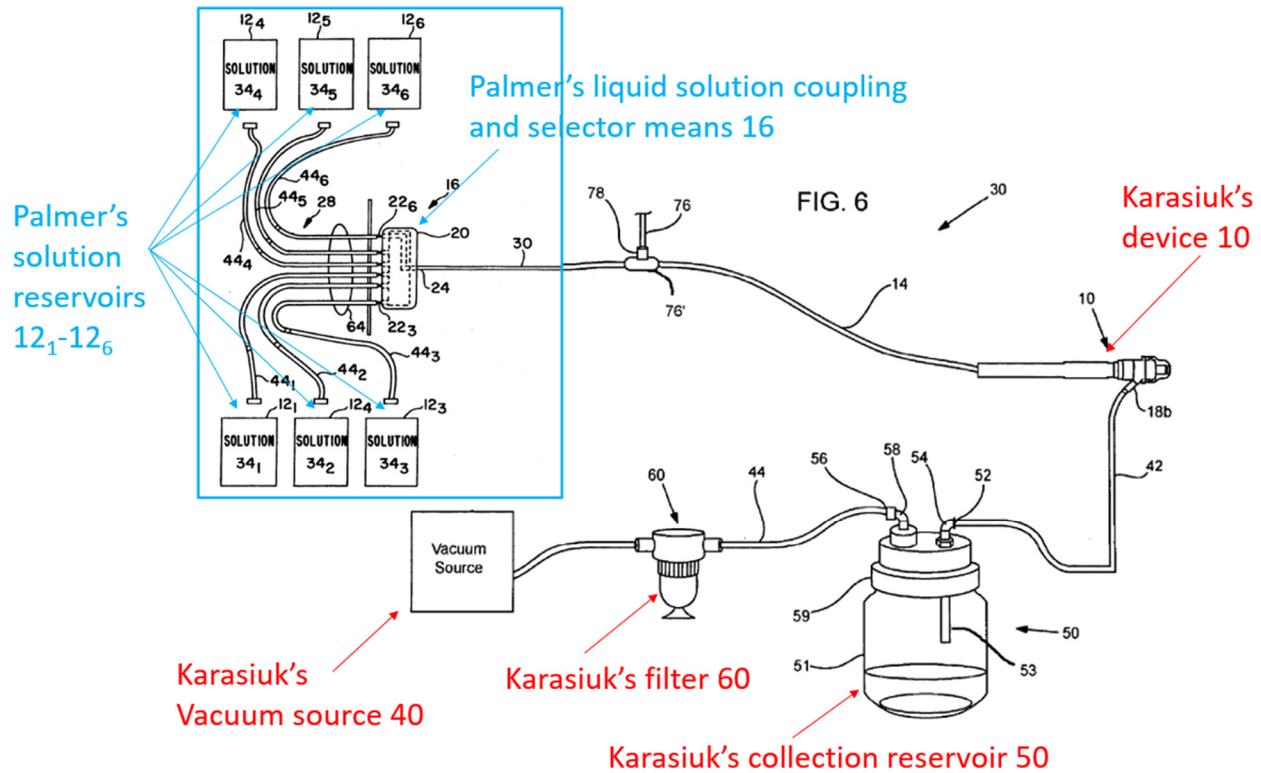
Wunsch, FIG. 1 (annotated)

104. Within the *console*, Karasiuk-Palmer describes a *manifold*¹ based on Palmer's teaching of "liquid solution coupling and selector means 16" that is included in the control unit enclosure 35 and configured for coupling handpiece means 14 to a selected one of the liquid solutions in a respective solution reservoir 12. EUNSUNG-1005, 4:60-63, 5:1-14. As shown in Palmer's FIG. 1 and Modified Karasiuk's FIG. 6, Palmer's "liquid solution coupling and selector means 16 include[s] 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." EUNSUNG-1005, 5:1-9.



Palmer, FIG. 1 (partial)

¹ The dictionary definition of "manifold" is "a chamber or pipe with many openings." EUNSUNG-1029, 5.



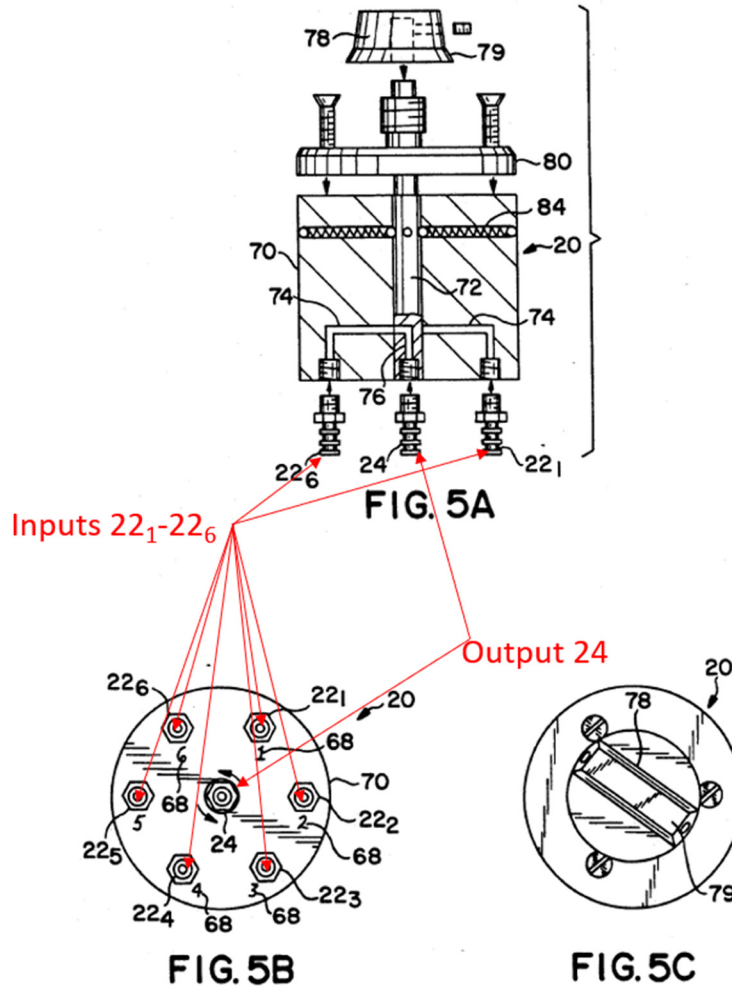
Karasiuk, Modified FIG. 6

105. Palmer's FIG. 4 shows an exploded view of control unit enclosure 35 including first tubing means 28, **selector valve means 20** (connected via valve inputs 22₁-22₆ to solution reservoirs 12₁-12₆), and selector knob 78. EUNSUNG-1005, 8:22-9:16, FIG. 4. The '052 patent also explains: "The manifold system 24 can have a modular design so that it can be removed from the console 12." EUNSUNG-1001, 17:53-54.



Palmer, FIG. 4

FIGS. 5A-5C.



Palmer, FIGS. 5A-5C

107. Referring to FIGS. 5A-5B, selector valve means 20 includes main body 70 defining multiple “liquid inlet passages 74” with multiple “input port[s] 22” and “liquid outlet passage 76” with “selector valve output port 24.” EUNSUNG-1005, 8:6-21. Further, main body 70 defines a “bore which receives the rotatable core 72 in a plane common with the inner ends of the other inlet passages 74.” *Id.* The “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.” *Id.*

108. This structure corresponds to the “manifold” described in the ’052 patent. Specifically, the ’052 patent recites: “The manifold system is 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. As shown in FIG. 1 of the ’052 patent, the “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” (e.g., via switches 29). EUNSUNG-1001, 17:5-7. Similar to the ’052 patent’s manifold system 24, Palmer’s liquid solution coupling and selector means 16 (including selector valve 20) is also designed to draw treatment fluid from at least one of Palmer’s containers 12₁-12₆ based on user selection (e.g., via selector knob 78). EUNSUNG-1005, 8:22-53 (“For example, when the knob is rotated so that the pointer 78 indicates the indicia designated ‘6,’ the outlet passage 76 communicates with the inlet passage 74 which opens into the inlet port 22₆ which is coupled to the solution 34₆ contained in the reservoir 12₆.”). Therefore, a POSITA would have understood and found obvious that (1) Palmer’s selector valve 20, (2) Palmer’s liquid solution coupling and selector means 16 (including the valve 20), or (3) Palmer’s control unit enclosure 35 (housing the coupling and selector means 16) correspond to, and perform the operations of, the *manifold*,

located within the “mobile cart 170” (*console*). EUNSUNG-1005, 9:58-10:16, 4:53-5:14, 8:22-9:16, FIG. 11B.

109. Notably, [1.1] does not require the manifold to “hold” the fluid containers, or that the manifold to be built into the console. Indeed, the definition of “manifold” includes “a chamber or pipe with many openings.” EUNSUNG-1029, 5. Thus, a POSITA would have understood and found obvious that Karasiuk-Palmer includes a manifold (e.g., Palmer’s liquid solution coupling and selector means 16) within the console (e.g., Palmer’s mobile cart 170).

110. Alternatively or in addition, a POSITA would have found it obvious to use a manifold to implement Palmer’s functionality of switching treatment fluids. Manifolds and their variants are foundational constructs within the art of fluidics and were well-known devices for selecting between or differentially combining different fluids and would have been within a POSITA’s general knowledge. Manifolded rotational and linear valve/switch components were common before the Critical Date. EUNSUNG-1010, FIGS. 2A-2G, 7A-7D, [0086] (“Manifold 26 contains a valve which controls the routing of fluid connections between patient port 84 and either syringe bottom port 80 or transducer/saline port 82.”), [0088]; EUNSUNG-1019, Abstract, 6:43-45 (“The ports, valves and conduits of the manifold may be configured in any manner that permits the desired flow of fluid through the manifold”), 10:30-44, FIGS. 7-10; EUNSUNG-1020,

Abstract (“Apparatus for sequentially dispensing a plurality of solutions through an intravenous supply catheter includes a disposable tubing manifold...”), 7:39-56, 8:17-26, FIGS. 1-4; EUNSUNG-1021, Abstract, 4:57-65, FIG. 1; EUNSUNG-1022, Abstract, FIGS. 1-4. Based on this general knowledge, a POSITA would have found it obvious to implement Palmer’s functionality using a manifold because manifolds were known to provide the combining function required, wherein multiple supply lines are combined (and may be valved) and connected to a single fluid output, as described by Palmer. Indeed, a POSITA would have viewed a manifold as one of a finite number of options to achieve the functionality described by Palmer that would have been obvious to try. First, based on Karasiuk and Palmer, a POSITA would have recognized a need to selectively dispense different treatment fluids. As discussed above in Section XI.1, Karasiuk recognizes the desirability of using multiple types of treatment solutions during microdermabrasion. EUNSUNG-1004, [0061]; 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.”). Karasiuk further discloses the use of manifolds for connections to containers in a microdermabrasion system. EUNSUNG-1004, [0056] (“manifold cover”), [0059] (“manifold”). Palmer also discloses using

selector knob 78 to selectively dispense different treatment solutions. EUNSUNG-1005, 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); 8:22-53.

Second, a POSITA would have understood that there were a finite number of identified, predictable solutions to selectively dispense treatment solutions from multiple containers, including (1) manually connecting/disconnecting the handpiece to different containers via one tube, (2) connecting the handpiece to each container via a separate valve-controlled tube, and (3) connecting the handpiece to multiple containers via a manifold (e.g., classic block style, a T-junction, or a Y-junction). A POSITA would have had “good reason to pursue the known options,” and thus, using a manifold would have been obvious to try.

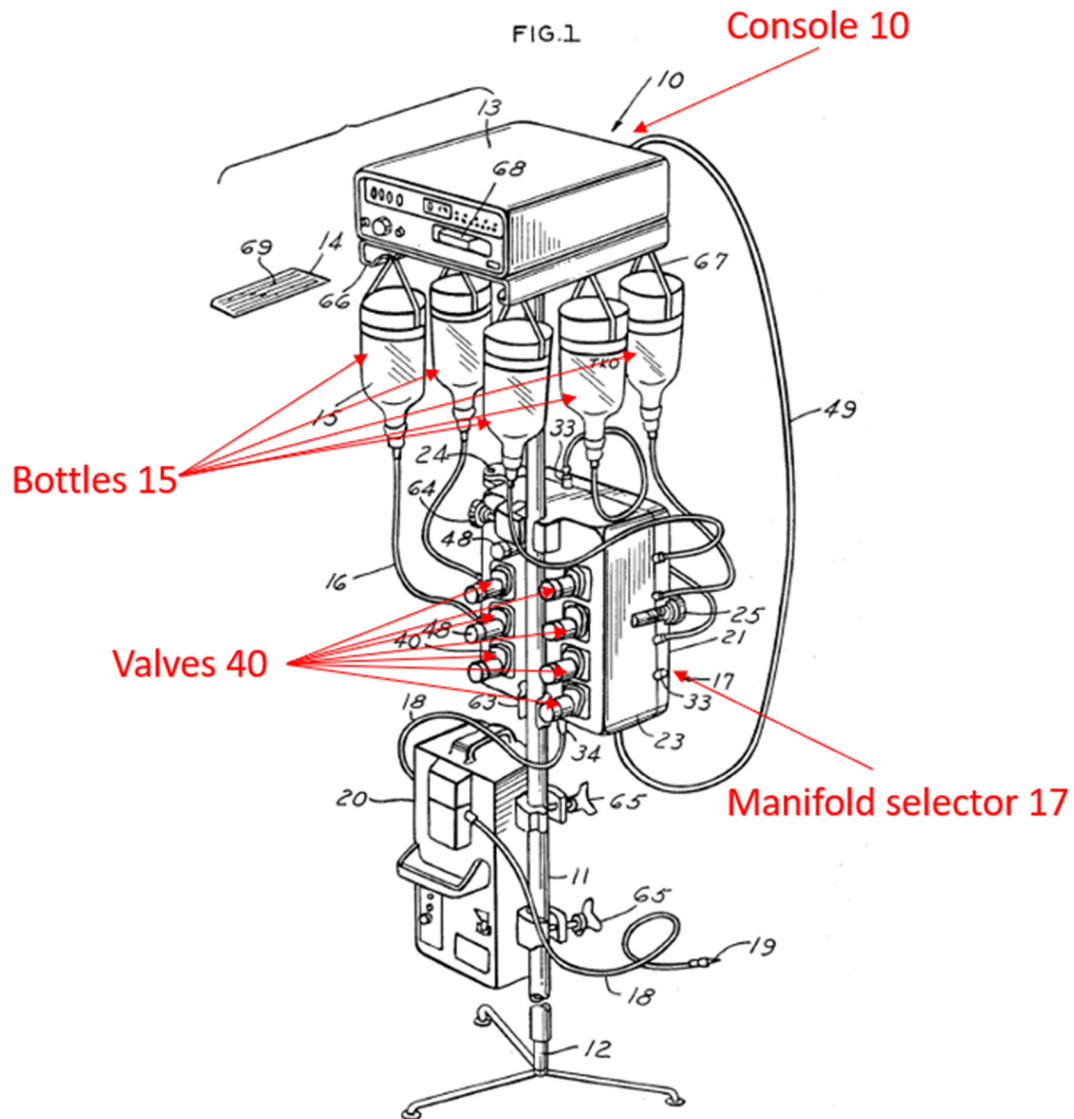
Further, a POSITA would have selected a manifold among this finite number of identified, predictable solutions because it eliminates the need of manual connecting/disconnecting and allows for a simpler handpiece design with one input.

111. Alternatively or in addition, using a manifold to implement Palmer’s functionality of switching treatment fluids would have been an obvious design choice without any unexpected results. As evidenced by Wunsch, using a manifold

to implement Palmer's functionality of switching treatment fluids yields expected results, and thus would have been an obvious matter of design choice within the skill of the art. EUNSUNG-1020, Abstract, 7:39-56, 8:17-26, FIGS. 1-4.

112. A POSITA would have had a reasonable expectation of success in implementing Palmer's switching between different fluids and providing a single fluid output using a manifold as it would have merely involved a simple substitution of one well-known element for another to obtain predictable results. For example, Duchon, Brengle, Wunsch, and Devos all disclose using a manifold to selectively dispense multiple treatment solutions. EUNSUNG-1010, [0086]-[0088], [0145]; EUNSUNG-1019, Abstract; EUNSUNG-1020, Abstract, FIG. 1; EUNSUNG-1021, Abstract, FIG. 1.

113. For 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.



Wunsch, FIG. 1 (annotated)

114. As discussed above in Section XI.1, and as shown in modified FIG. 6 of Karasiuk, Karasiuk-Palmer describes that the manifold (e.g., Palmer's liquid solution coupling and selector means 16) is in fluid communication with six solution reservoirs (e.g., Palmer's solution reservoirs 12₁-12₆) which would have

been understood as including a *first fluid container and at least a second container*. Section XI.1; EUNSUNG-1005, 5:1-18.

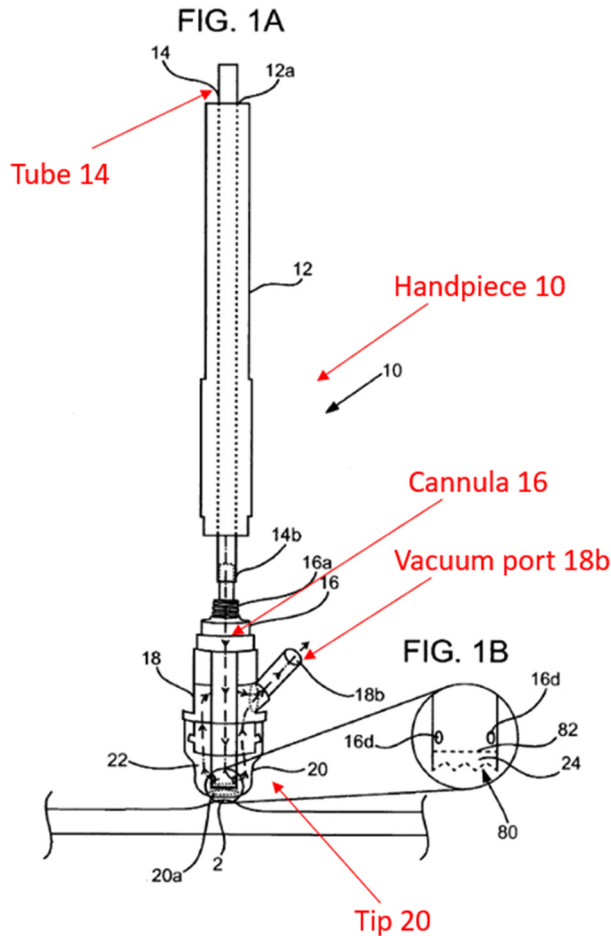
115. Also, Palmer discloses that its six solution reservoirs each include “a respective liquid solution” (*liquid*) with a unique color coding. EUNSUNG-1005, 4:53-57, 5:37-6:32. Karasiuk also recognizes the desirability of using multiple types of liquid skin treatment solutions during microdermabrasion (*skin treatment procedure*). EUNSUNG-1004, [0024], [0047], [0061]. Thus, in Karasiuk-Palmer, it would have been obvious to use Palmer’s multiple containers to hold different treatment liquids as taught by Karasiuk and Palmer—for example, a first container holding an antioxidant formulation and a second container holding a hydrating formulation. 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.”).

[1.2] a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;

116. It is my opinion that Karasiuk-Palmer renders obvious a handpiece

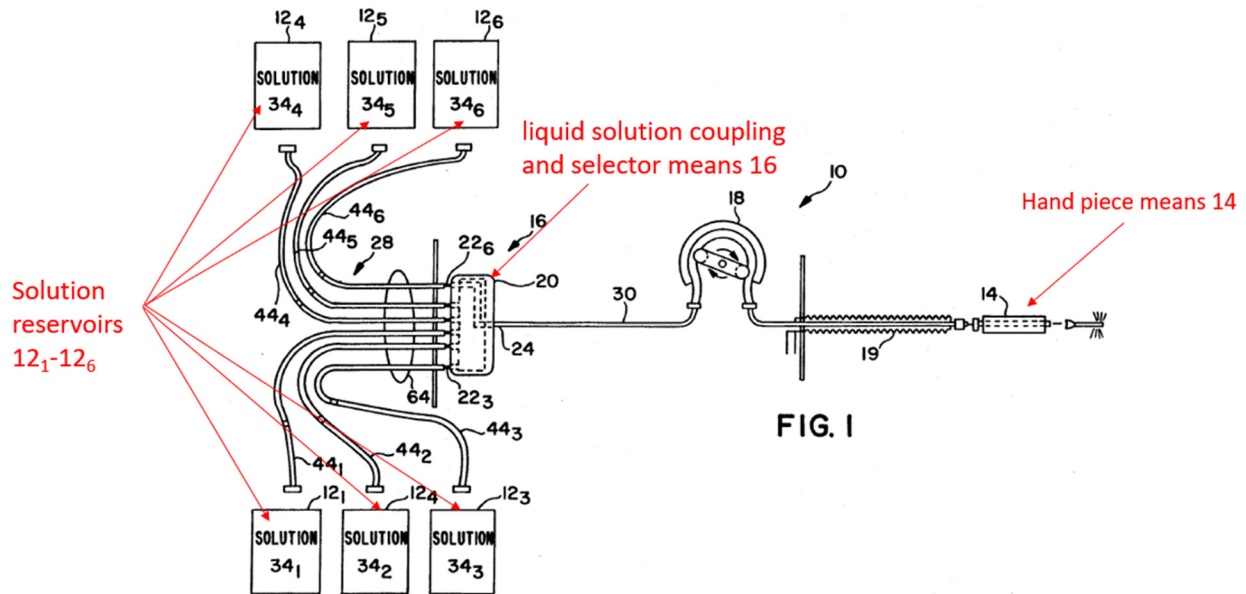
assembly comprising a tip, the tip being configured to contact a skin surface of a subject. For example, Karasiuk's "[d]evice 10 is designed to be **handheld by a user** for its application to the skin of a patient in the performance of microdermabrasion or other vacuum therapy application." EUNSUNG-1004, [0044] ("an elongated handle 12 to facilitate grasping by a user"), [0045] ("Cannula 16 runs through the center of the handpiece"). Thus, Karasiuk-Palmer includes a handpiece assembly configured to contact skin tissue of a subject, such as Karasiuk's "[d]evice 10" (FIG. 6) designed to be "**handheld by a user** for its application to the skin of a patient." EUNSUNG-1004, [0044]-[0047], [0063]. Karasiuk's "treatment tip 20 is fitted over the end of vacuum head base 18" and "is smooth surfaced and adapted to glide over the skin surface for application of lotions/vitamins or other fluids thereto during processing." EUNSUNG-1004, [0047]. Karasiuk also discloses "device 10 is positioned so as to place tip 20 **in contact with the skin surface.**" EUNSUNG-1004, [0063].

117. 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)

118. Similarly, Palmer describes “handpiece means 14” (FIG. 1) for “delivering a selected one of the liquid solutions contained in one of the reservoirs 12 directly to a treatment site.” EUNSUNG-1005, 4:57-60. Palmer illustrates this handpiece means 14 in FIG. 1. EUNSUNG-1005, 4:50-68, FIG. 1.



Palmer, FIG. 1 (annotated)

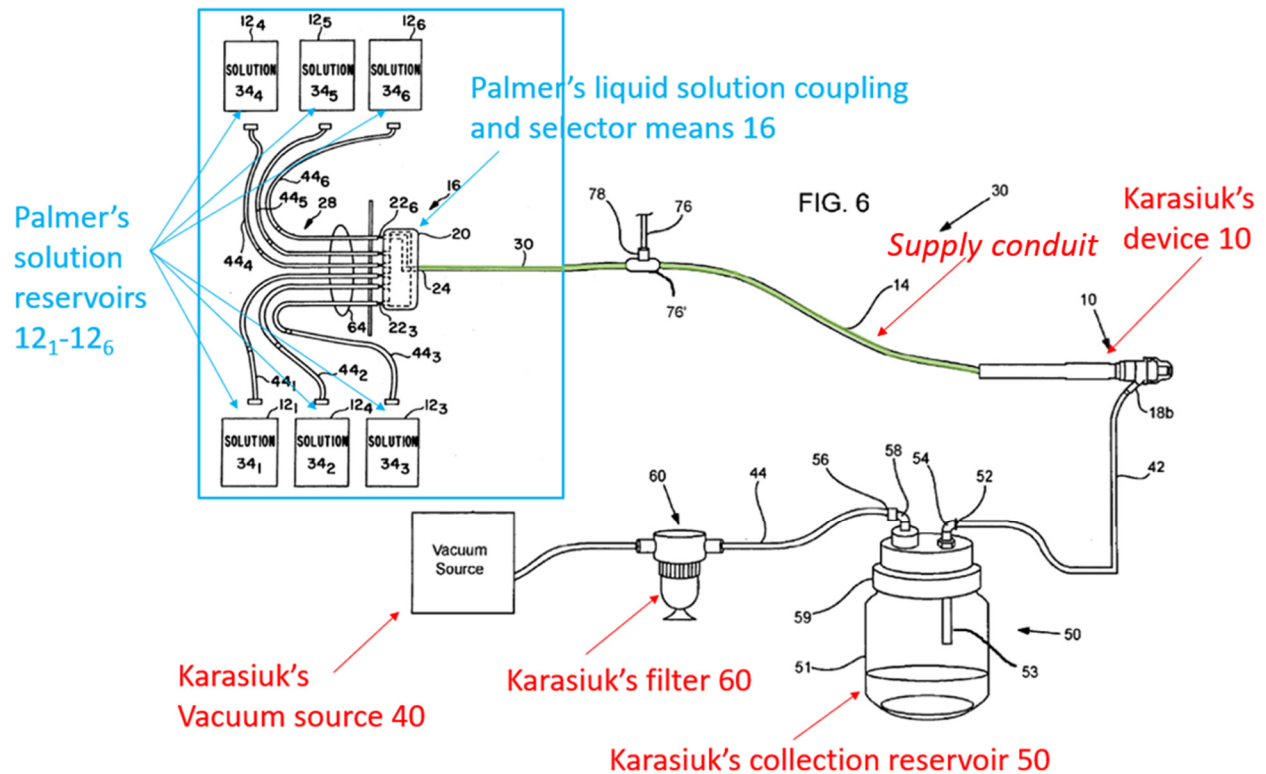
119. Palmer's FIG. 8 also shows "a handpiece means and an associated applicator tip." EX1005, 4:35-37. Thus, Karasiuk-Palmer renders obvious a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject.

[1.3] a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly;

120. It is my opinion that Karasiuk-Palmer renders obvious a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly. As discussed above in [1.1], a POSITA would have understood and found obvious that (1) Palmer's selector valve 20, (2) Palmer's liquid solution coupling and selector means 16 (including the valve 20),

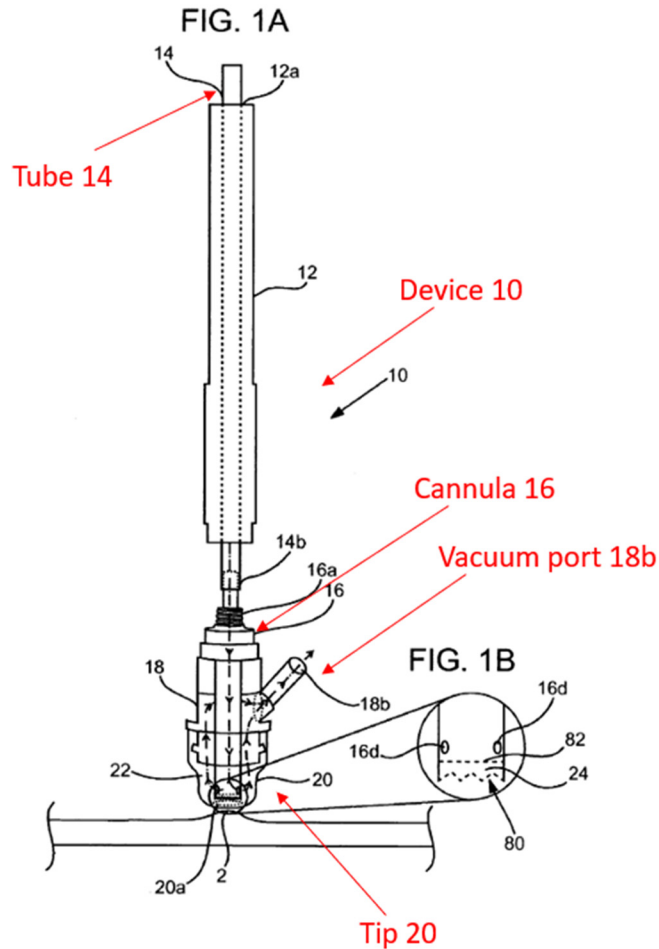
or (3) Palmer's control unit enclosure 35 (housing the coupling and selector means 16) correspond to, and perform the operations of, the *manifold*.

121. As discussed above in Section XI.1, in Karasiuk-Palmer, instead of being connected to single reservoir 70, Karasiuk's tube 14 (e.g., upstream of breather line 76) would replace, or be connected to, Palmer's second tubing means 30 to achieve benefits resulting from selection of different treatment solutions. EUNSUNG-1004, [0020], [0056], [0064]-[0066]. Thus, in Karasiuk-Palmer, a supply conduit (e.g., Karasiuk's tube 14 or collectively Palmer's second tubing means 30, Karasiuk's T joint 76', and Karasiuk's tube 14) places the manifold (e.g., Palmer's liquid solution coupling and selector means 16) in fluid communication with the handpiece assembly (e.g., Karasiuk's device 10). *Id.*; EUNSUNG-1005, 5:1-18.



Karasiuk, Modified FIG. 6

122. As shown in modified FIG. 6 and FIG. 1A, a distal end of the supply conduit (e.g., Karasiuk's tube 14 or collectively Palmer's second tubing means 30, Karasiuk's T joint 76', and Karasiuk's tube 14) is configured to couple to the handpiece assembly (e.g., Karasiuk's device 10). EUNSUNG-1004, [0044] ("Handle 12 is annular or tubular, providing a passageway 12a through which tube 14 is extended"), [0045] ("The distal end 14b of tube 14 is connected to cannula 16, Cannula 16 is adapted to be fixed to handle 12"), [0059] ("Tube 14 extends from the proximal end of the microdermabrasion device 10"), FIGS. 1A and 6.

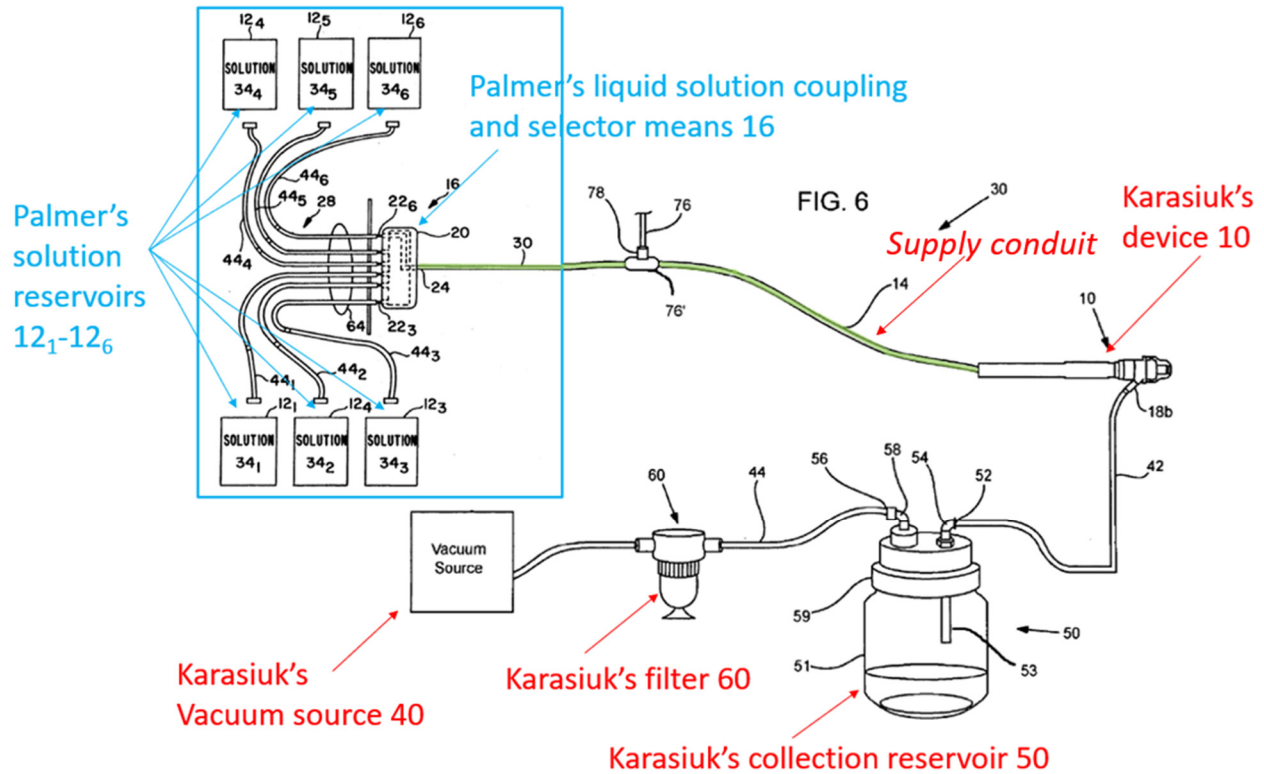


Karasiuk, FIG. 1A

[1.4] wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; and

123. It is my opinion that Karasiuk-Palmer renders obvious that the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit. As discussed in [1.1] and [1.3], Palmer's solution reservoirs (*the first fluid container and at least the second fluid container*) are each connected to Palmer's "liquid solution coupling and selector means 16" (*manifold*), which is connected to

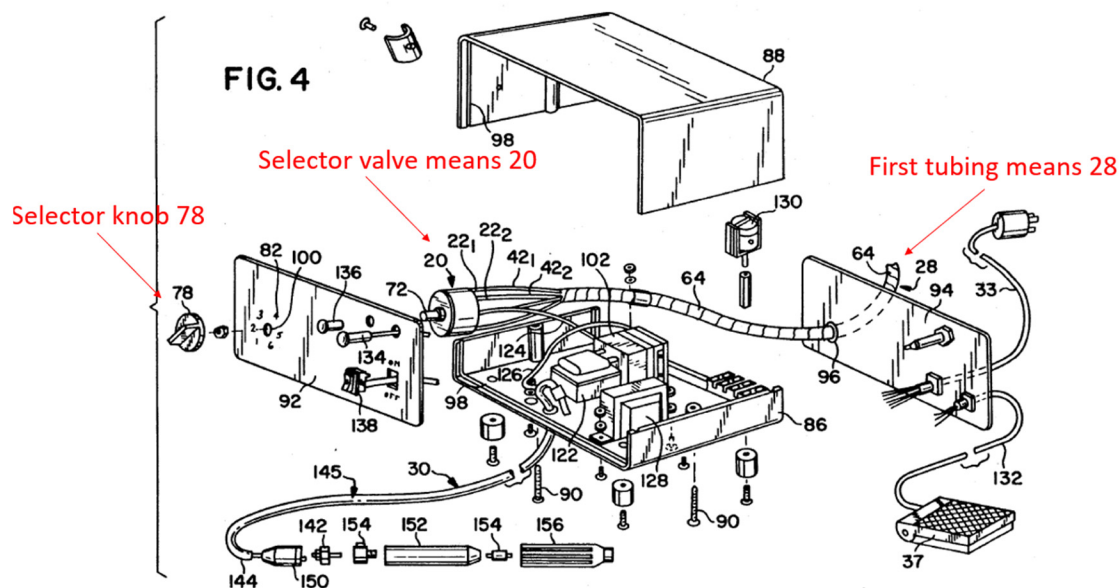
Karasiuk's handpiece via a **supply conduit** (e.g., Karasiuk's tube 14 or collectively Palmer's second tubing means 30, Karasiuk's T joint 76', and Karasiuk's tube 14).



Karasiuk, Modified FIG. 6

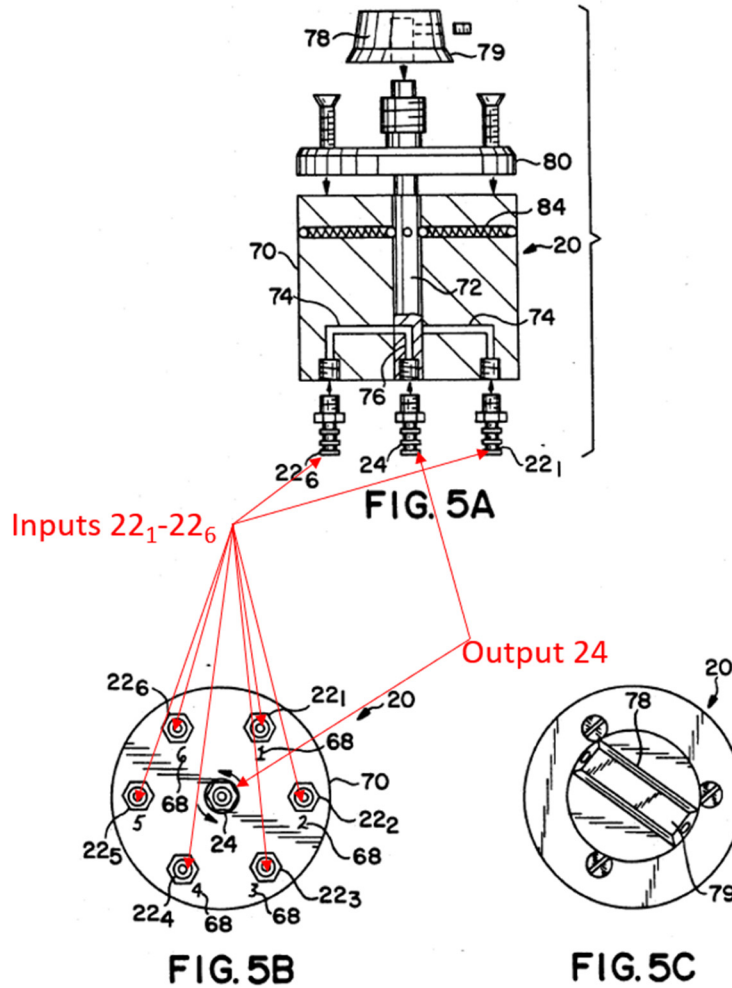
124. As discussed in Section XI.1, in Karasiuk-Palmer, Karasiuk's reservoir 70 is replaced with Palmer's multiple reservoirs and "liquid solution coupling and selector means 16" to allow selection of different treatment solutions.

125. Palmer's FIG. 4 shows an exploded view of control unit enclosure 35 including first tubing means 28, **selector valve means 20** (connected via valve inputs 22₁-22₆ to solution reservoirs 12₁-12₆), and selector knob 78. EUNSUNG-1005, 8:22-9:16, FIG. 4.



Palmer, FIG. 4

126. Palmer illustrates an exemplary selector valve means 20 in
FIGS. 5A-5C.



Palmer, FIGS. 5A-5C

127. Referring to FIGS. 5A-5B, selector valve means 20 includes main body 70 defining multiple “liquid inlet passages 74” with multiple “input port[s] 22” and “liquid outlet passage 76” with “selector valve output port 24.” EUNSUNG-1005, 8:6-21. Further, main body 70 defines a “bore which receives the rotatable core 72 in a plane common with the inner ends of the other inlet passages 74.” *Id.* The “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

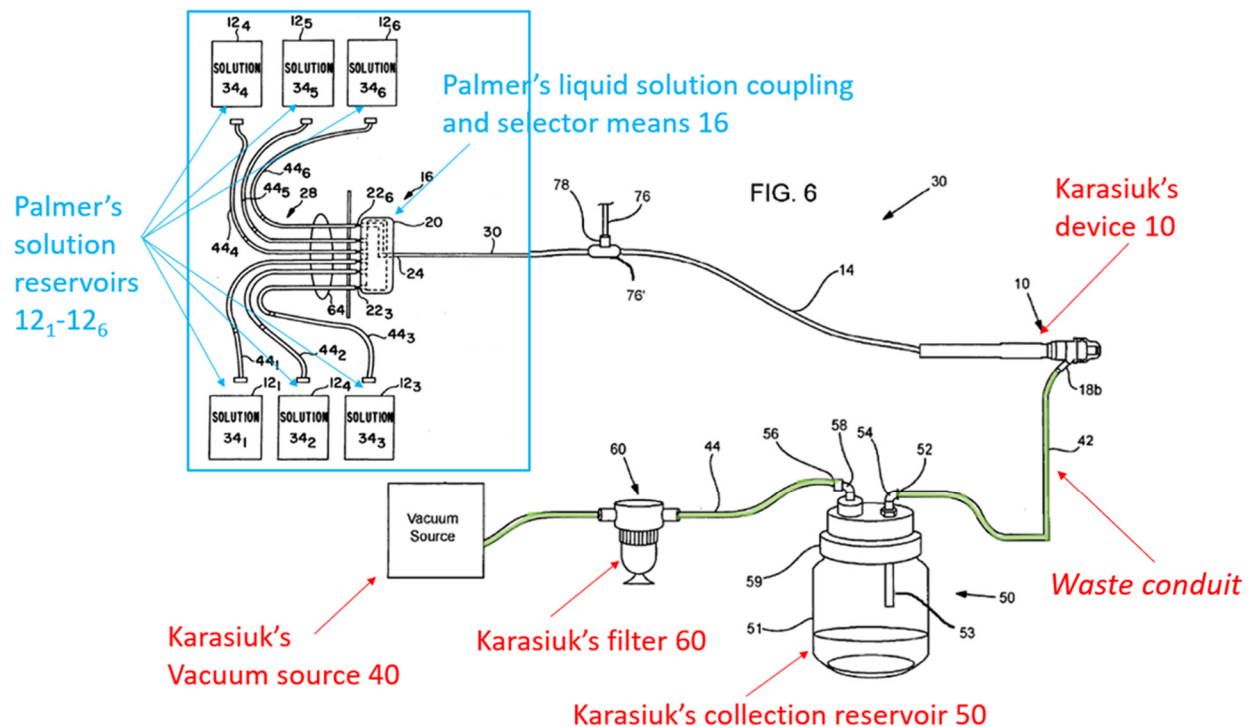
opening onto the cylindrical core surface in the plane of the inner ends of passages.” *Id.* This structure corresponds to (or renders obvious in combination with a POSITA’s general knowledge as discussed at [1.1]) the “manifold” described in the ’052 patent. In operation, by turning selector knob 78, the manifold selectively connects the handpiece (e.g., Karasiuk’s device 10) to a selected solution reservoir. EUNSUNG-1005, 8:22-53 (“For example, when the knob is rotated so that the pointer 78 indicates the indicia designated ‘6,’ the outlet passage 76 communicates with the inlet passage 74 which opens into the inlet port 22₆ which is coupled to the solution 34₆ contained in the reservoir 12₆.”).

128. Thus, in Karasiuk-Palmer, a POSITA would have understood that the manifold (e.g., Palmer’s liquid solution coupling and selector means 16) is configured to control a flow of treatment material from the first fluid container (e.g., Palmer’s solution reservoir 12₁) and at least the second fluid container (e.g., Palmer’s solution reservoir 12₂) through the supply conduit (e.g., Karasiuk’s tube 14 or collectively Palmer’s second tubing means 30, Karasiuk’s T joint 76’, and Karasiuk’s tube 14).

[1.5] a vacuum source;

129. It is my opinion that Karasiuk-Palmer renders obvious a vacuum source. As discussed in Section XI.1, in Karasiuk-Palmer, Karasiuk’s vacuum source would be used to pump treatment solutions from Palmer’s multiple fluid

containers and collect waste/debris. EUNSUNG-1004, [0020], [0056], [0064]-[0066]. Instead of being connected to single reservoir 70, Karasiuk's tube 14 (e.g., upstream of breather line 76) would replace, or be connected to, Palmer's second tubing means 30 to achieve benefits resulting from selection of different treatment solutions. *Id.* In the resulting system, the vacuum source performs pumping the treatment solution and removing waste/debris, according to Karasiuk. *Id.*; EUNSUNG-1004, [0020], [0056], [0064]-[0066].



Karasiuk, Modified FIG. 6

[1.6] a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source; and

130. It is my opinion that Karasiuk-Palmer renders obvious a waste conduit

in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source. As discussed in Section XI.1, in Karasiuk-Palmer, Karasiuk's vacuum source would be used to pump treatment solutions from Palmer's multiple fluid containers and collect waste/debris. EUNSUNG-1004, [0020], [0056], [0064]-[0066]. For example, Karasiuk discloses "[a]s the flow of 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].

131. Karasiuk discloses in relevant part:

[0056] FIG. 6 shows an example of a microdermabrasion system 30 according to the present invention, which incorporates device 10 or 10' (though only device 10 is shown). Vacuum opening 18b is connected with a vacuum source 40 as described above, by vacuum line 42. **A collection reservoir 50 and, optionally, an inline filter 60 are connected in the vacuum line between device 10 and vacuum source 40.** Vacuum line 42 connects to an input 52 to collection reservoir 50 via elbow 54, for example, and output 56 connects with a second vacuum line 44 via elbow 58, for example. A manifold cover 59 sealably interfaces the input (52,54) and output (56,58) connections with a reservoir 51 which is typically a jar made of glass or plastic for example. **An extension tube 53 connects with input 52,54 and extends into the reservoir 51 to ensure effective delivery of waste materials (abraded skin particles and, optionally, fluids) to reservoir 51.**

EUNSUNG-1004, [0056].

132. Karasiuk further discloses in relevant part:

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.

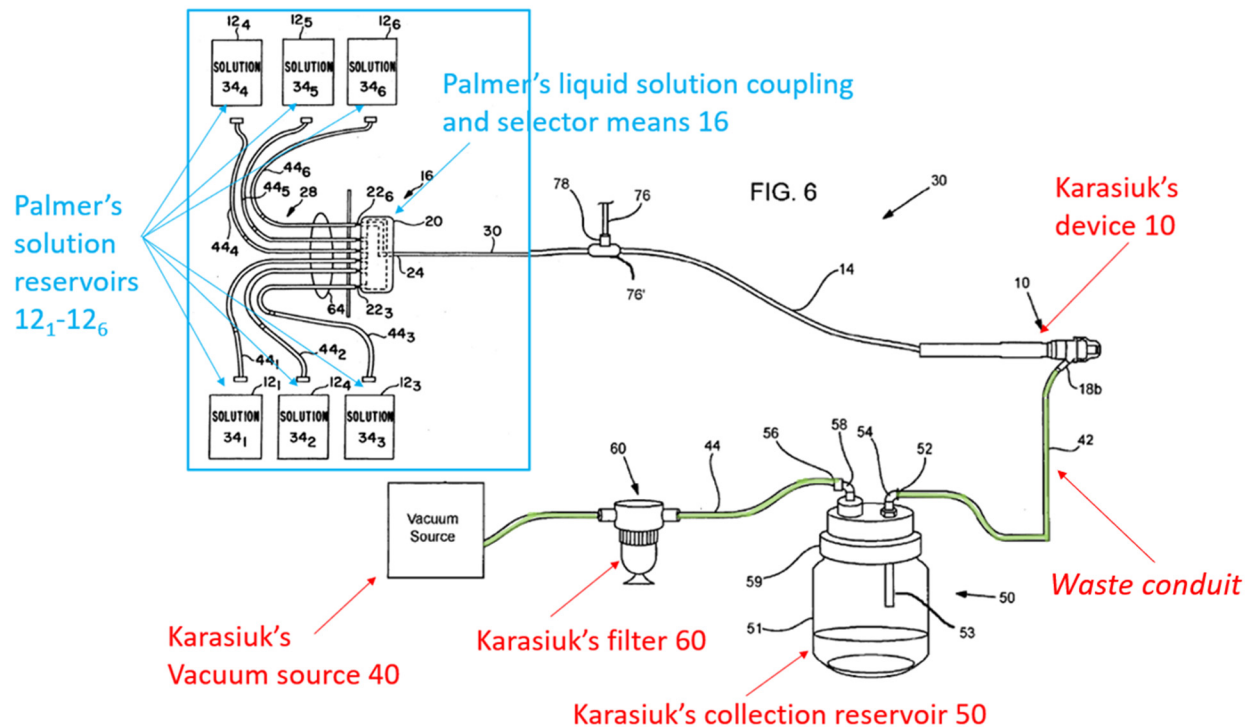
...

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].

133. As shown in FIG. 1A of Karasiuk and modified FIG. 6 of Karasiuk, in Karasiuk-Palmer, the tip (e.g., Karasiuk's tip 20) of the handpiece assembly (e.g., Karasiuk's device 10) has a "[v]acuum opening 18b" that is in fluid

communication with “vacuum source 40” through the “vacuum line between device 10 and vacuum source 40” (e.g., collectively vacuum line 42, second vacuum line 44, vacuum line 46) (respectively or collectively a *waste conduit*).
EUNSUNG-1004, [0056], FIGS. 1A and 6; EUNSUNG-1005, 4:50-68, 9:58-10:2, FIGS. 1, 11B.



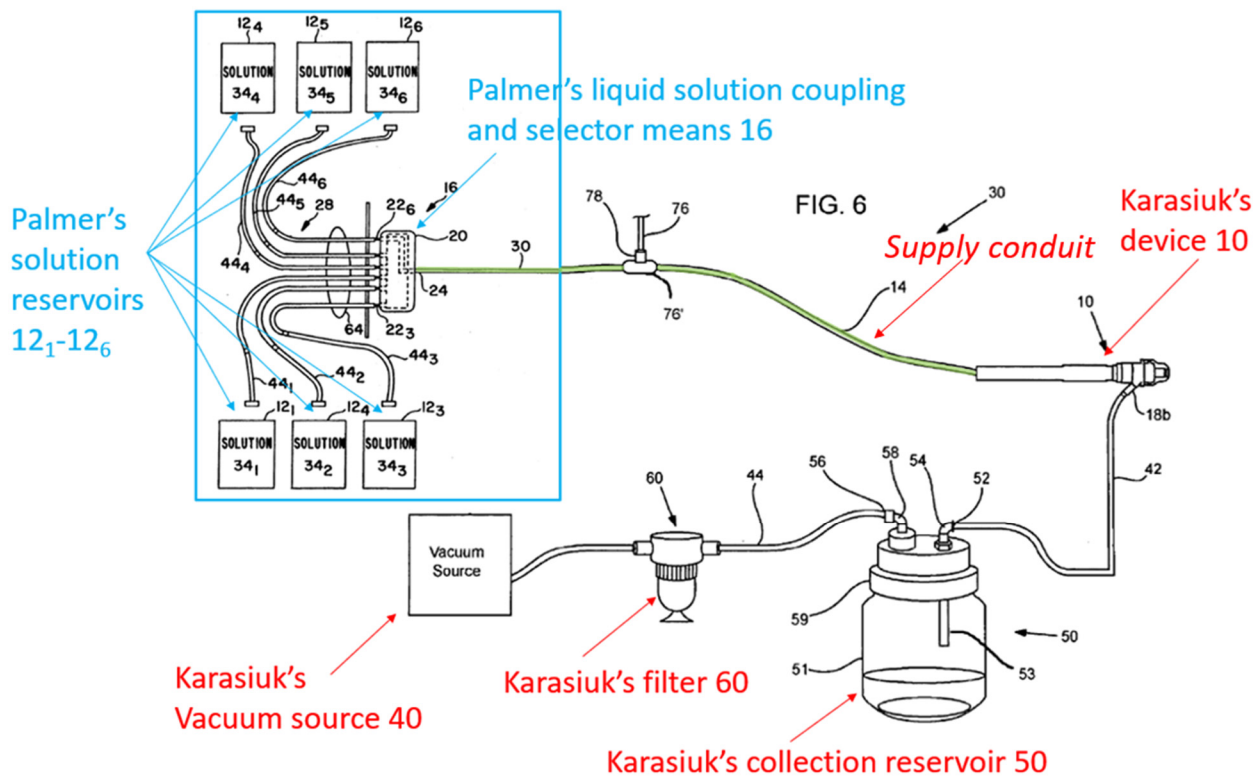
Karasiuk, Modified FIG. 6

134. Thus, in Karasiuk-Palmer, as shown in Karasiuk's modified FIG. 6, a POSITA would have understood and found obvious that the system includes a waste conduit (e.g., Karasiuk's “vacuum line between device 10 and vacuum source 40” or collectively Karasiuk's vacuum line 42, second vacuum line 44, vacuum line 46) that is in fluid communication with the tip of the handpiece

assembly (e.g., Karasiuk's device 10) to remove waste away from a skin surface of a subject during microdermabrasion (*a skin treatment procedure*), wherein the waste conduit is operatively coupled to the vacuum source (e.g., Karasiuk's vacuum source 40).

[1.7] wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly; and

135. It is my opinion that Karasiuk-Palmer renders obvious that the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly. As discussed in Section XI.1, in Karasiuk-Palmer, Karasiuk's reservoir 70 is replaced with Palmer's multiple reservoirs and "liquid solution coupling and selector means 16" to allow selection of different treatment solutions. Karasiuk discloses that upon forming a vacuum loop, the fluid contents in the fluid reservoir are "drawn through tube 14 and into device 10...and are applied to the skin." EUNSUNG-1004, [0064].



Karasiuk, Modified FIG. 6

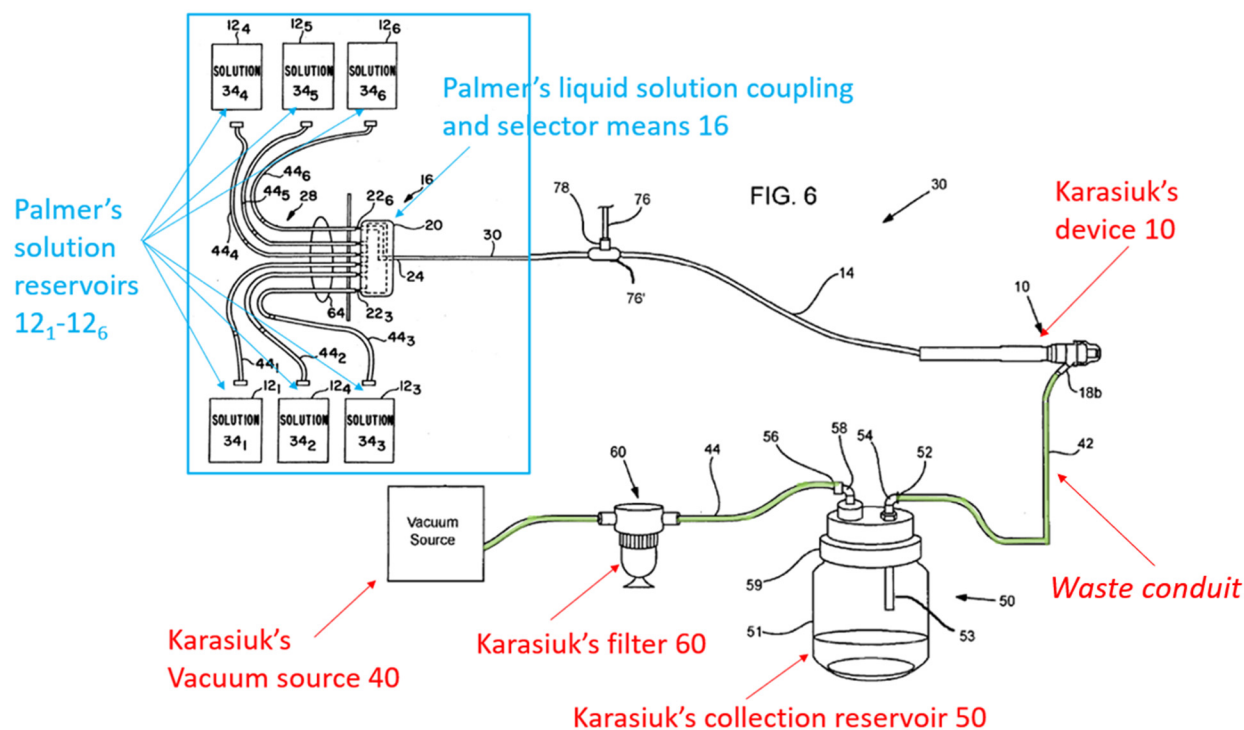
136. As discussed in [1.4], in operation, by turning selector knob 78, the manifold (e.g., Palmer's liquid solution coupling and selector means 16) selectively connects the handpiece (e.g., Karasiuk's device 10) to a selected solution reservoir. EUNSUNG-1005, 8:22-53 ("For example, when the knob is rotated so that the pointer 78 indicates the indicia designated '6,' the outlet passage 76 communicates with the inlet passage 74 which opens into the inlet port 22₆ which is coupled to the solution 34₆ contained in the reservoir 12₆.").

137. Thus, a POSITA would have understood and found obvious that Karasiuk-Palmer's system is configured to permit a user to select (e.g., by turning

Palmer's selector knob 78) the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly.

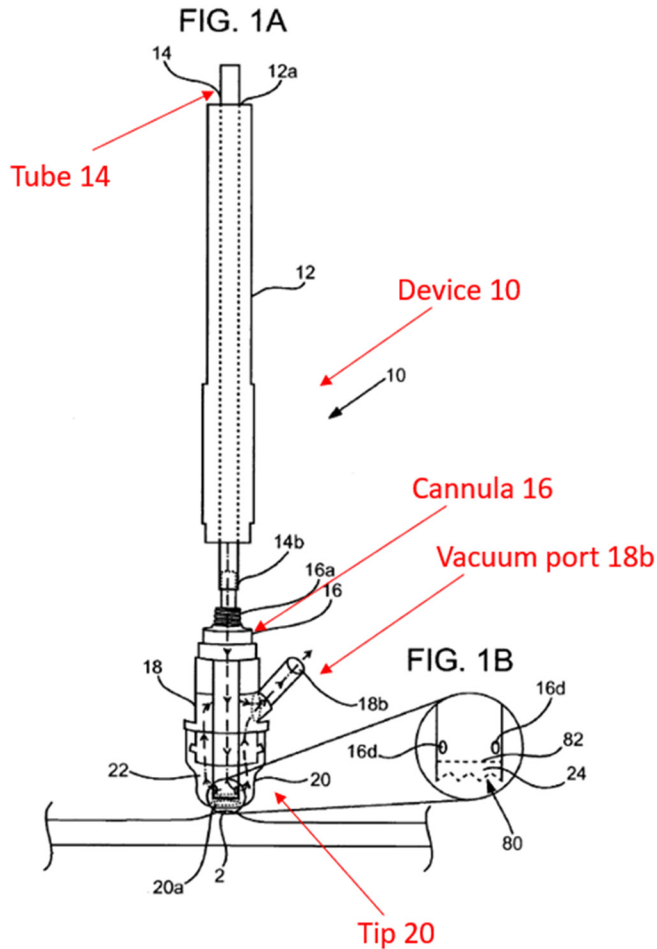
[1.8] wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

138. It is my opinion that Karasiuk-Palmer renders obvious that when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit. As discussed in Section XI.1, in Karasiuk-Palmer, Karasiuk's *vacuum source* 40 is connected to collection reservoir 50 and device 10 (*handpiece assembly*) to remove waste/debris as well as to draw treatment solutions from Palmer's fluid containers. EUNSUNG-1004, [0020], FIG. 6.



Karasiuk, Modified FIG. 6

139. “When vacuum is applied through opening 18b, an opening 20a is sealed off, for example **by placing it up against the skin tissue**, a closed loop vacuum flow path is established between the vacuum source and connecting line, vacuum opening 18b, annulus 22, opening(s) 16d, passageway 16c and tube 14.” EUNSUNG-1004, [0054], FIGS. 1A and 6. Upon forming a vacuum loop, the fluid contents in the fluid reservoir are “drawn through tube 14 and into device 10...and are applied to the skin.” EUNSUNG-1004, [0064]. “As the flow of 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].



Karasiuk, FIG. 1A

140. Karasiuk discloses in relevant part:

[0056] FIG. 6 shows an example of a microdermabrasion system 30 according to the present invention, which incorporates device 10 or 10' (though only device 10 is shown). Vacuum opening 18b is connected with a vacuum source 40 as described above, by vacuum line 42. **A collection reservoir 50 and, optionally, an inline filter 60 are connected in the vacuum line between device 10 and vacuum source 40.** Vacuum line 42 connects to an input 52 to collection reservoir 50 via elbow 54, for example, and output 56 connects with a second vacuum line 44 via elbow 58, for example. A manifold cover 59 sealably interfaces the input (52,54) and output (56,58) connections with a reservoir 51 which is typically a jar made of glass or plastic for example. **An**

extension tube 53 connects with input 52,54 and extends into the reservoir 51 to ensure effective delivery of waste materials (abraded skin particles and, optionally, fluids) to reservoir 51.

EUNSUNG-1004, [0056].

141. Thus, a POSITA would have understood and found obvious that when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit (e.g., Karasiuk’s “vacuum line between device 10 and vacuum source 40” or collectively Karasiuk’s vacuum line 42, second vacuum line 44, vacuum line 46) and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

3. Claim 4

[4] The system of claim 1, wherein the first fluid container or the at least a second fluid container is releasably coupled to the manifold.

142. It is my opinion that Karasiuk-Palmer renders obvious that the first fluid container or the at least a second fluid container is releasably coupled to the manifold. As discussed in Section XI.1, in Karasiuk-Palmer, instead of being connected to single reservoir 70, Karasiuk’s tube 14 (e.g., upstream of breather line 76) would replace, or be connected to, Palmer’s second tubing means 30 to achieve benefits resulting from selection of different treatment solutions. EUNSUNG-1004, [0020], [0056], [0064]-[0066].

143. As discussed in [1.1] and [1.4], in Karasiuk-Palmer, the manifold

(e.g., Palmer's liquid solution coupling and selector means 16) is in fluid communication with a first fluid container and at least a second fluid container.

144. Palmer further discloses that Palmer's second tubing means 30 is connected to each of Palmer's six solution reservoirs via a "**quick-disconnect** right angle membrane-penetrating adapter 40" which "is connected to the end of each of the tubes 42 for **quick-disconnect connection** to the membrane cap 38 of a respective reservoir to pierce the membrane, thereby coupling each tube to the solution contained in that reservoir." EUNSUNG-1005, 7:34-39. Thus, a POSITA would have understood and found obvious that, in Karasiuk-Palmer, each of Palmer's six solution reservoirs (*the first fluid container or the at least a second fluid container*) is releasably coupled to the manifold.

4. Claim 5

[5] The system of claim 1, wherein the manifold is configured to be placed in fluid communication with at least four fluid containers.

145. It is my opinion that Karasiuk-Palmer renders obvious that the manifold is configured to be placed in fluid communication with at least four fluid containers. As discussed in Section XI.1, in Karasiuk-Palmer, Karasiuk's reservoir 70 is replaced with Palmer's multiple reservoirs and "liquid solution coupling and selector means 16" to allow selection of different treatment solutions.

146. As discussed above in Section XI.1 and as shown in modified FIG. 6 of Karasiuk, Karasiuk-Palmer includes six solution reservoirs (e.g., reservoirs 12₁-

12₆) in fluid communication with the manifold (e.g., Palmer's liquid solution coupling and selector means 16). EUNSUNG-1005, 5:1-18. Thus, a POSITA would have understood and found obvious that, in Karasiuk-Palmer, the manifold is configured to be placed in fluid communication with at least four fluid containers.

5. Claim 6

[6] The system of claim 1, wherein treatment materials from the first fluid container and at least the second fluid container are delivered to the supply conduit sequentially or simultaneously.

147. It is my opinion that Karasiuk-Palmer renders obvious that the treatment materials from the first fluid container and at least the second fluid container are delivered to the supply conduit sequentially or simultaneously. As discussed in Section XI.1, Karasiuk-Palmer 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, 4:50-63, 8:6-21, FIGS. 1, 5A-5C. As discussed in [1.6], the reservoirs in the combination contain different solutions. EUNSUNG-1005, 4:50-63.

148. In operation, “a patient may be treated with two or more solutions during the same procedure, **one after the other**,” and “[w]hen treatment with the particular irrigating solution is completed, **the system can be ... switched to another solution**.” EUNSUNG-1005, 6:46-51, 11:9-12. Karasiuk recognizes

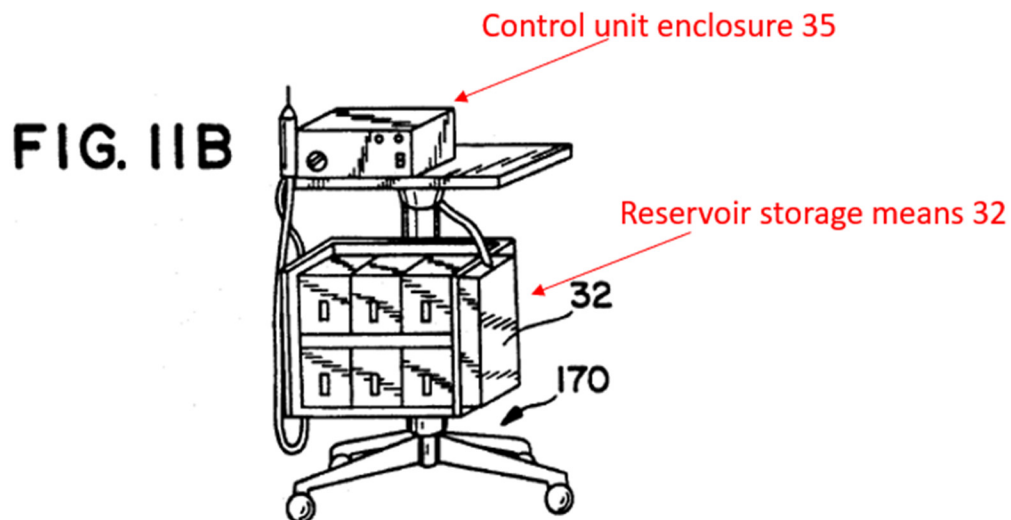
desirability of using multiple types of skin treatment solutions during microdermabrasion. EUNSUNG-1004, [0024], [0047], [0061]. Therefore, the Karasiuk-Palmer system would have used Palmer's multiple containers to *sequentially* deliver different skin treatment solutions—for example, a first container holding an antioxidant formulation (e.g., vitamin) and a second container holding a hydrating formulation (e.g., lotion). Section XI.1; 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.”).

149. Alternatively, a POSITA would have found it obvious to configure Karasiuk-Palmer to achieve sequential or simultaneous delivery of treatment fluids from the first fluid container and at least the second fluid container. For example, Trueba discloses: “... one 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.” Trueba, 11:21-24.

6. Claim 7

[7] The system of claim 1, wherein the console is movable.

150. It is my opinion that Karasiuk-Palmer renders obvious that the console is movable. As discussed in [1.1] above, the Karasiuk-Palmer system includes a **console** in the form of, for example, “mobile cart 170” that receives Palmer’s multiple containers (reservoir storage means 32 receiving multiple reservoirs) and selector means (control unit enclosure 35), and also receives Karasiuk’s handheld device 10, collection reservoir 50, vacuum source 40, and other relevant components in a modular structure. Section XI.1; EUNSUNG-1005, 9:58-10:2, FIGS. 11A-11C. A POSITA would have understood and found obvious that this console is movable at least because Palmer’s FIG. 11B shows that this “mobile cart 170” is placed on four casters.



Palmer, FIG. 11B

7. Claim 8

[8] The system of claim 1, wherein the tip of the handpiece assembly is configured to exfoliate skin tissue as the handpiece assembly is moved relative to a skin surface of a subject.

151. It is my opinion that Karasiuk-Palmer renders obvious that the tip of the handpiece assembly is configured to exfoliate skin tissue as the handpiece assembly is moved relative to a skin surface of a subject. As discussed in [1.5] and [1.6] above, in Karasiuk-Palmer, the tip (e.g., Karasiuk's tip 20) of the handpiece (e.g., Karasiuk's device 10) defines "opening or port 18b" for "connection of a vacuum source ... via a vacuum line" and to remove "the exfoliated skin particles and any other waste" from the handheld device. EUNSUNG-1004, [0054], [0066], [0047], FIG. 1A. Karasiuk discloses that upon forming a vacuum loop, "[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 skin is drawn into contact with abrasive member 24." EUNSUNG-1004, [0064]. As the user of 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." EUNSUNG-1004, [0064]. "As the flow of 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]. 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.

152. Thus, a POSITA would have understood and found obvious that the tip 20 (*tip*) of Karasiuk's handheld device 10 (*handpiece assembly*) is configured to exfoliate skin tissue as the handpiece assembly is moved relative to a skin surface of a subject.

8. Claim 9

[9] The system of claim 1, wherein each of the supply conduit and the waste conduit connects to a corresponding connector along a proximal end of the handpiece assembly.

153. It is my opinion that Karasiuk-Palmer renders obvious that each of the supply conduit and the waste conduit connects to a corresponding connector along a proximal end of the handpiece assembly. As discussed above for [1.3], in Karasiuk-Palmer, a supply conduit places the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly. EUNSUNG-1004, FIG. 6. Connecting the supply conduit and the waste conduit to a corresponding connector along a proximal end of the handpiece assembly (e.g., by locating Karasiuk's vacuum port 18b at a proximal end of the handpiece assembly) would have been an obvious design choice because it is merely the rearrangement of parts

without any “difference in function” or “unexpected results.” As evidenced by Mercier, doing this yields expected results without altering the function of the Karasiuk-Palmer system, and thus would have been an obvious matter of design choice within the skill of the art.

154. Alternatively or in addition, locating Karasiuk’s vacuum port 18b on a proximal end of the handpiece assembly would have been obvious to try. A POSITA would have recognized a finite number of identified, predictable locations to locate Karasiuk’s vacuum port 18b: at a proximal end of the handpiece assembly (similar to Mercier’s FIG. 4), at a middle point between the proximal end and the distal end (similar to Karasiuk’s FIG. 1), or at a distal end of the handpiece assembly. A POSITA would have had “good reason to pursue the known options,” and thus, connecting the supply conduit and the waste conduit to a corresponding connector along a proximal end of the handpiece assembly (e.g., by locating Karasiuk’s vacuum port 18b at a proximal end of the handpiece assembly) would have been obvious to try.

9. Claim 10

[10] The system of claim 1, wherein the manifold of the console is configured to be placed in fluid communication with a container comprising an antimicrobial fluid or other disinfecting agent for periodic flushing of the manifold.

155. It is my opinion that Karasiuk-Palmer renders obvious that the manifold of the console is configured to be placed in fluid communication with a

container comprising an antimicrobial fluid or other disinfecting agent for periodic flushing of the manifold. As discussed in [1.1], in Karasiuk-Palmer, the manifold (e.g., Palmer's liquid solution coupling and selector means 16) of the console (e.g., Palmer's mobile cart 170) is configured to be placed in fluid communication with a first fluid container and at least a second fluid container.

156. As discussed above in Section XI.1, 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). Among the listed treatment solutions, Karasiuk discloses using "antiseptics" and "cleansers." EUNSUNG-1004, [0061].

157. Further, Palmer discloses that its solution reservoir 12₁ may contain an **"aqueous bacteriostatic rinse solution for use as a flush."** EUNSUNG-1005, 5:52-55. Palmer also discloses that "[t]he apparatus enables the handpiece tubing and handpiece to be flushed with the flush solution prior to shutting off the unit." EUNSUNG-1005, 11:14-16. A POSITA would have understood and found obvious that by flushing the handpiece, Palmer's bacteriostatic rinse solution will also flush the manifold (e.g., Palmer's liquid solution coupling and selector means 16).

158. Thus, in Karasiuk-Palmer, a POSITA would have found it obvious that the manifold of the console is configured to be placed in fluid communication with a container comprising an antimicrobial fluid (e.g., Palmer's bacteriostatic rinse solution) or other disinfecting agent for periodic flushing of the manifold.

10. Claim 11

[11.pre] A system for performing a skin treatment procedure, the system comprising:

159. It is my opinion that Karasiuk-Palmer renders obvious a system for performing a skin treatment procedure. *See* [1.pre].

[11.1] a manifold in fluid communication with at least two fluid containers, each of the at least two fluid containers being configured to contain a treatment material, wherein the treatment material comprises a liquid;

160. It is my opinion that Karasiuk-Palmer renders obvious a manifold in fluid communication with at least two fluid containers, each of the at least two fluid containers being configured to contain a treatment material, wherein the treatment material comprises a liquid. *See* [1.1].

[11.2] a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;

161. It is my opinion that Karasiuk-Palmer renders obvious a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject. *See* [1.2].

[11.3] a supply conduit placing the manifold in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to

secure to the handpiece assembly;

162. It is my opinion that Karasiuk-Palmer renders obvious a supply conduit placing the manifold in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to secure to the handpiece assembly. *See* [1.3]. As discussed in [1.3], in Karasiuk-Palmer, a POSITA would have understood and found obvious that a distal end of the supply conduit is configured to “couple” to the handpiece assembly. For the same reasons, a POSITA would have understood and found obvious that a distal end of the supply conduit is configured to “secure” to the handpiece assembly.² EUNSUNG-1004, [0044] (“Handle 12 is annular or tubular, providing a passageway 12a through which tube 14 is extended”), [0045] (“The distal end 14b of tube 14 is connected to cannula 16, Cannula 16 is adapted to be fixed to handle 12”), [0059] (“Tube 14 extends from the proximal end of the microdermabrasion device 10”), FIGS. 1A and 6. A POSITA would have understood and found obvious that, for the supply conduit to deliver treatment solutions to the handpiece, it needs to be securely connected to the handpiece. *Id.*

[11.4] a vacuum source; and

163. It is my opinion that Karasiuk-Palmer renders obvious a vacuum source. *See* [1.5].

² The specification of the '052 patent does not use the term “secure.”

[11.5] a waste conduit in fluid communication with the handpiece assembly to remove waste from a skin surface of a subject during a procedure, wherein the waste conduit is operatively coupled to the vacuum source;

164. It is my opinion that Karasiuk-Palmer renders obvious a waste conduit in fluid communication with the handpiece assembly to remove waste from a skin surface of a subject during a procedure, wherein the waste conduit is operatively coupled to the vacuum source. *See* [1.6].

[11.6] wherein the manifold is configured to control a flow of treatment material from each of the at least two fluid containers through the supply conduit;

165. It is my opinion that Karasiuk-Palmer renders obvious that the manifold is configured to control a flow of treatment material from each of the at least two fluid containers through the supply conduit. *See* [1.4].

[11.7] wherein the system is configured to permit a user to select the fluid container from which treatment material is delivered to the supply conduit.

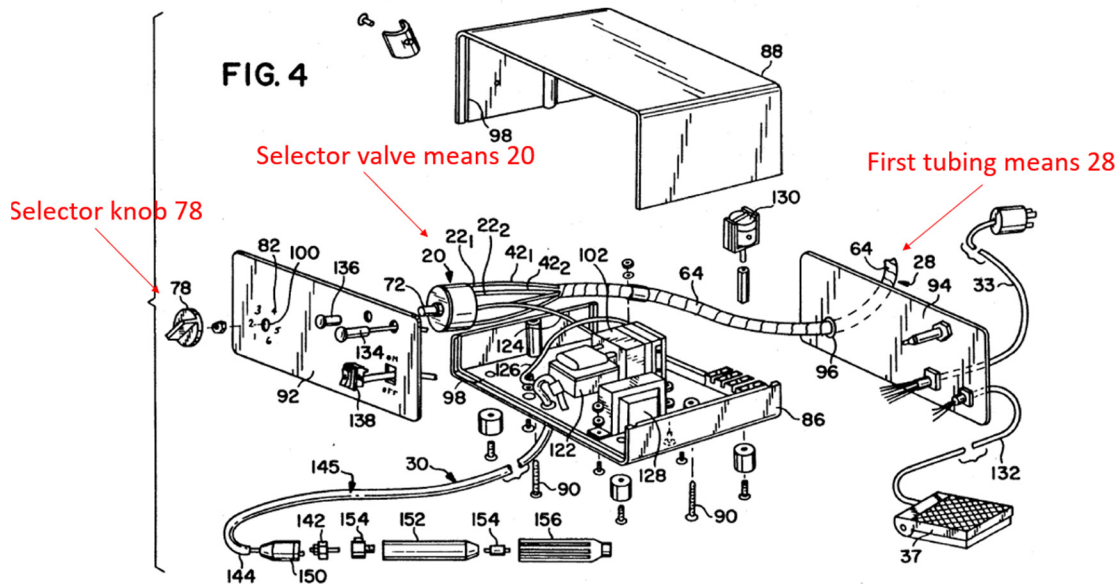
166. It is my opinion that Karasiuk-Palmer renders obvious that the system is configured to permit a user to select the fluid container from which treatment material is delivered to the supply conduit. *See* [1.7].

11. Claim 12

[12] The system of claim 11, further comprising a user input device for selecting a treatment material to be passed through the supply conduit to the handpiece assembly.

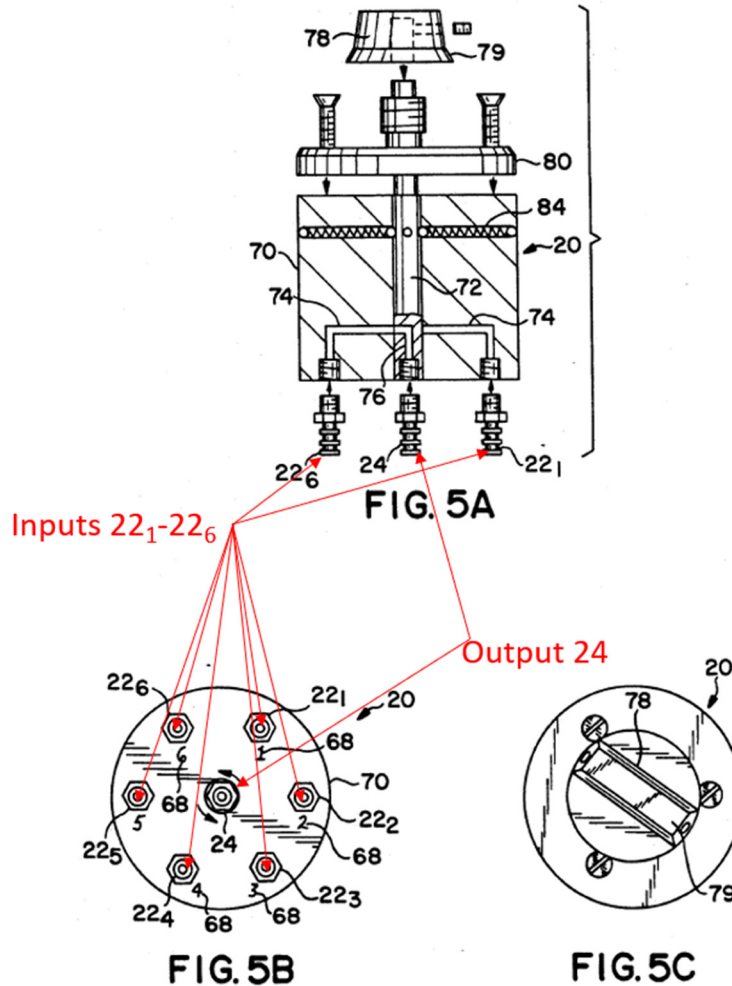
167. It is my opinion that Karasiuk-Palmer renders obvious a user input device for selecting a treatment material to be passed through the supply conduit to the handpiece assembly. Palmer discloses a user input device in the form of a

selector knob 78. EUNSUNG-1005, 8:22-9:16, FIG. 4. Palmer's FIG. 4 shows an exploded view of control unit enclosure 35 including first tubing means 28, **selector valve means 20** (connected via valve inputs 22₁-22₆ to solution reservoirs 12₁-12₆), and selector knob 78. EUNSUNG-1005, 8:22-9:16, FIG. 4.



Palmer, FIG. 4

168. Palmer illustrates an exemplary selector valve means 20 in FIGS. 5A-5C.



Palmer, FIGS. 5A-5C

169. Referring to FIGS. 5A-5B, selector valve means 20 includes main body 70 defining multiple “liquid inlet passages 74” with multiple “input port[s] 22” and “liquid outlet passage 76” with “selector valve output port 24.” EUNSUNG-1005, 8:6-21. Further, main body 70 defines a “bore which receives the rotatable core 72 in a plane common with the inner ends of the other inlet passages 74.” *Id.* The “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.” *Id.* In operation, by turning selector knob 78, the manifold selectively connects the handpiece (e.g., Karasiuk’s device 10) to a selected solution reservoir. EUNSUNG-1005, 8:22-53 (“For example, when the knob is rotated so that the pointer 78 indicates the indicia designated ‘6,’ the outlet passage 76 communicates with the inlet passage 74 which opens into the inlet port 22₆ which is coupled to the solution 34₆ contained in the reservoir 12₆.”).

170. Thus, a POSITA would have understood or found obvious that Karasiuk-Palmer includes a user input device (e.g., Palmer’s selector knob 78) for selecting a treatment material to be passed through the supply conduit to the handpiece assembly.

12. Claim 15

[15] The system of claim 11, wherein the at least two fluid containers is releasably coupled to the manifold.

171. It is my opinion that Karasiuk-Palmer renders obvious that the at least two fluid containers is releasably coupled to the manifold. *See* [4].

13. Claim 16

[16] The system of claim 11, wherein the tip of the handpiece assembly is configured to exfoliate skin tissue as the handpiece assembly is moved relative to a skin surface of a subject.

172. It is my opinion that Karasiuk-Palmer renders obvious that the tip of the handpiece assembly is configured to exfoliate skin tissue as the handpiece

assembly is moved relative to a skin surface of a subject. *See* [8].

14. Claim 17

[17] The system of claim 11, wherein the manifold is configured to be placed in fluid communication with a container comprising an antimicrobial fluid or other disinfecting agent for periodic flushing of the manifold.

173. It is my opinion that Karasiuk-Palmer renders obvious that the manifold is configured to be placed in fluid communication with a container comprising an antimicrobial fluid or other disinfecting agent for periodic flushing of the manifold. *See* [10].

XII. [GROUND 1B]: Karasiuk-Palmer-Trueba

1. Karasiuk-Palmer-Trueba Combination

174. 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'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 device (e.g., Trueba's touch screen 105 and/or computer 115), 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.

175. 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 to apply things in a wrong order.

176. 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.

177. 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.

178. 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.

179. 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.

180. 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 device (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.

181. 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.

182. 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.

183. In addition, Trueba discloses sequential or simultaneous delivery of treatment fluids from the first container and at least one additional container: “... one 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.” Trueba 11:21-24.

184. 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.

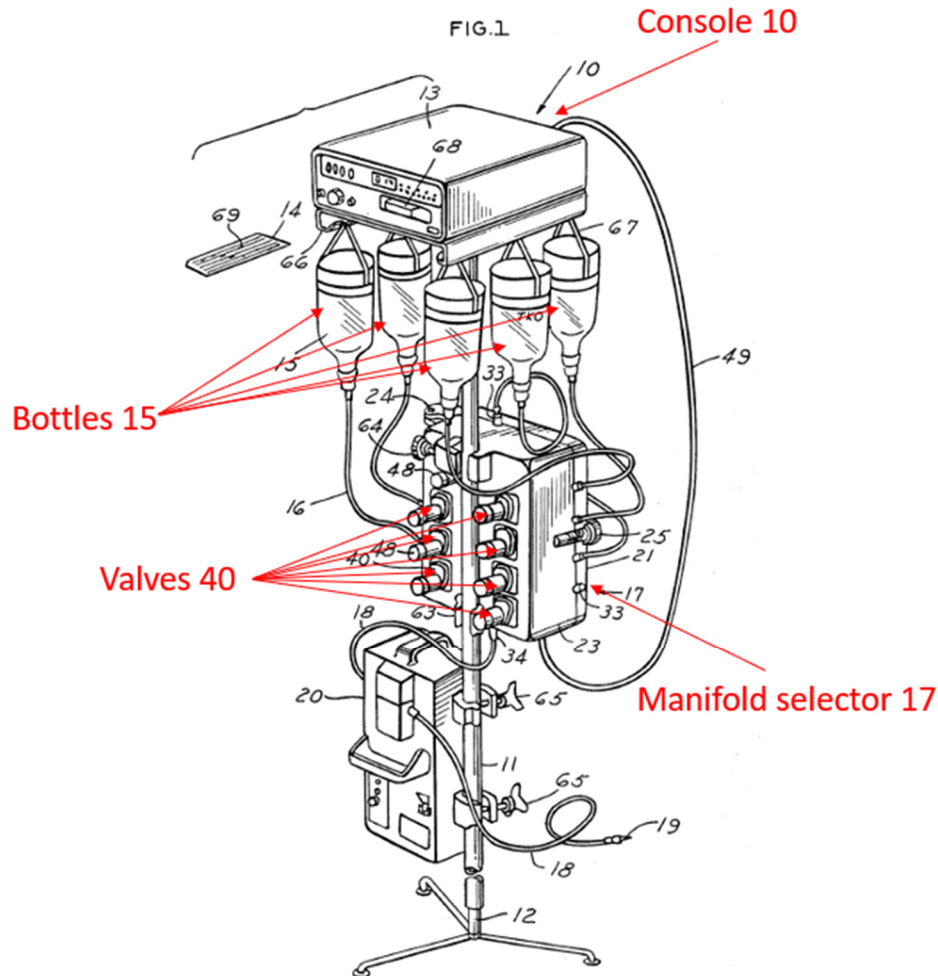
185. By the Critical Date, computer (e.g., PLC) controlled fluid delivery systems were well-known. EUNSUNG-1007, FIG. 3; EUNSUNG-1008, FIG. 3; EUNSUNG-1015, Abstract. Compared to manually controlled systems, computer controlled systems provide added precision and automation (e.g., automated delivery 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.

186. 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.

187. 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)

188. 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.

189. 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 device (e.g., Trueba's touch

screen 105 or computer 115), 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, 4-12, 15-17

190. As discussed in Section XI above, Karasiuk-Palmer-Trueba renders obvious claims 1, 4-12, 15-17 for the same reasons as discussed regarding Karasiuk-Palmer.

3. Claim 2

[2] The system of claim 1, wherein the console comprises a display, wherein the display comprises a user input device to facilitate controlling a flow of treatment materials from the first fluid container or the at least a second fluid container to the handpiece assembly.

191. It is my opinion that Karasiuk-Palmer-Trueba renders obvious that the console comprises a display, wherein the display comprises a user input device to facilitate controlling a flow of treatment materials from the first fluid container or the at least a second fluid container to the handpiece assembly. As discussed in Section XI, Karasiuk-Palmer-Trueba renders obvious claim 1 for the same reasons as discussed regarding Karasiuk-Palmer. Karasiuk-Palmer-Trueba further renders obvious [2] based on Trueba's teachings.

192. As discussed in Section XII, Karasiuk-Palmer-Trueba's system includes a display indicating which solution is being delivered, and that the display

can be a user input device (e.g., Trueba's touch screen 105) to select a flow of fluids from containers to the handpiece. EUNSUNG-1008, 11:40-12:8, FIG. 3. Further, as discussed in Section XII, a POSITA would have understood and found it obvious to place the touch screen in the console to provide added flexibility, organization, and portability. EUNSUNG-1008, FIG. 3. Thus, in Karasiuk-Palmer-Trueba, a POSITA would have understood and found obvious that the console comprises a display (e.g., Trueba's display 105), wherein the display comprises a user input device (e.g., Trueba's touch screen 105) to facilitate controlling a flow of treatment materials from the first fluid container or the at least a second fluid container to the handpiece assembly.

4. Claim 3

[3] The system of claim 2, wherein the user input device comprises a touch screen.

193. It is my opinion that Karasiuk-Palmer-Trueba renders obvious that the user input device comprises a touch screen. As discussed in Section XII, Karasiuk-Palmer-Trueba's user input device includes a touch screen. EUNSUNG-1008, 11:40-12:8, FIG. 3.

5. Claim 6

[6] The system of claim 1, wherein treatment materials from the first fluid container and at least the second fluid container are delivered to the supply conduit sequentially or simultaneously.

194. It is my opinion that Karasiuk-Palmer-Trueba renders obvious that

treatment materials from the first fluid container and at least the second fluid container are delivered to the supply conduit sequentially or simultaneously. As discussed in Section XI, Karasiuk-Palmer-Trueba renders obvious claim 6 for the same reasons as discussed regarding Karasiuk-Palmer.

195. Karasiuk-Palmer-Trueba further renders obvious [6] based on Trueba's teachings. To the extent that the term "sequentially" is interpreted to require automatic switching between first and second treatment fluids, 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. As discussed in Section XII, 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. Trueba also discloses simultaneous delivery of treatment fluids and allows user programming of sequential or simultaneous delivery. EUNSUNG-1008, 11:4-49. A POSITA would have found it obvious to employ Trueba's automation in the system of Karasiuk-Palmer to provide added precision (avoiding human error), automation, and clarity, resulting in automatic switching and delivery of treatment fluids in a sequential or simultaneous manner.

6. Claim 12

[12] The system of claim 11, further comprising a user input device for selecting a treatment material to be passed through the supply conduit to the handpiece

assembly.

196. It is my opinion that Karasiuk-Palmer-Trueba renders obvious a user input device for selecting a treatment material to be passed through the supply conduit to the handpiece assembly. *See* [2].

197. As discussed in Section XI, Karasiuk-Palmer-Trueba renders obvious claim 11 for the same reasons as discussed regarding Karasiuk-Palmer. Karasiuk-Palmer-Trueba further renders obvious [12] based on Trueba's teachings.

198. As discussed in Section XII, Karasiuk-Palmer-Trueba's system includes a display indicating which solution is being delivered, and that the display can be a user input device (e.g., Trueba's touch screen 105) to select a flow of fluids from containers to the handpiece. EUNSUNG-1008, 11:40-12:8, FIG. 3. Thus, in Karasiuk-Palmer-Trueba, a POSITA would have understood and found obvious that the system includes a user input device (e.g., Trueba's touch screen 105) for selecting a treatment material to be passed through the supply conduit to the handpiece assembly.

7. Claim 13

[13] The system of claim 11, wherein the system comprises a display, wherein the display comprises a user input device to facilitate controlling a flow of treatment materials from the at least two fluid containers.

199. It is my opinion that Karasiuk-Palmer-Trueba renders obvious that the system comprises a display, wherein the display comprises a user input device to facilitate controlling a flow of treatment materials from the at least two fluid

containers. *See* [2].

8. Claim 14

[14] The system of claim 13, wherein the user input device comprises a touch screen.

200. It is my opinion that Karasiuk-Palmer-Trueba renders obvious that the user input device comprises a touch screen. *See* [3].

XIII. [GROUND 1C]: Karasiuk-Palmer-Mercier

1. Karasiuk-Palmer-Mercier

201. It is my opinion that a POSITA would have been motivated to combine Karasiuk, Palmer, and Mercier with a reasonable expectation of success. In Karasiuk-Palmer-Mercier, Karasiuk-Palmer's handpiece (e.g., Karasiuk's device 10) would be replaced by Mercier's handpiece (e.g., Mercier's hand tool 1). Specifically, Mercier's supply channel 17 would be connected to a supply conduit (e.g., Karasiuk's tube 14 or collectively Palmer's second tubing means 30, Karasiuk's T joint 76', and Karasiuk's tube 14) and Mercier's evacuating channel 21 would be connected to a waste conduit (e.g., Karasiuk's "vacuum line between device 10 and vacuum source 40" or collectively Karasiuk's vacuum line 42, second vacuum line 44, vacuum line 46). EUNSUNG-1017, 4:56-61.

202. Several reasons would have prompted a POSITA to modify Karasiuk-Palmer's system based on Mercier's teachings. As discussed in Section XI.1, Karasiuk-Palmer's system uses a handpiece for applying a fluid treatment solution

to a treatment site and a vacuum for collecting waste during microdermabrasion.

EUNSUNG-1004, Abstract, [0044]-[0045], [0056]-[0059], [0063]-[0066], FIG. 6.

Thus, both Karasiuk-Palmer and Mercier are directed to a microdermabrasion device with a handpiece for applying a fluid treatment solution to a treatment site and a vacuum for collecting waste during microdermabrasion. EUNSUNG-1004, Abstract, [0013]-[0015], FIG. 6; EUNSUNG-1017, Abstract. Based on general knowledge and Mercier's disclosure, a POSITA would have recognized the desirability of using Mercier's rotation-inducing means. EUNSUNG-1017, 2:11-14 and 11:61-12:15. 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 use of Mercier's handpiece design to improve Karasiuk-Palmer's system.

203. First, as explained by Mercier, a major problem associated with traditional handpiece design is that the hand tool is devised to project the abrasive stream onto the skin surface to be removed at a tilted angle, which gives rise to an abrasion pattern on the skin surface in the form of an undesirable "half-moon" pattern. EUNSUNG-1017, 1:43-51. In order to avoid this "half-moon" pattern, a POSITA would have been motivated to adopt Mercier's handpiece design with a "rotation inducing mechanism." EUNSUNG-1017, 10:62-66 ("Another substantial

improvement of the present invention, as also explained hereinabove, is that the hand tool 1 enables a **substantially more even skin abrasion pattern** than what is possible with the devices known in the prior art, both in surface geometry and in time.”).

204. Second, as explained by Mercier, another problem with traditional handpiece design is that it requires handpieces to be operated at an optimal tilted angle with respect to the skin surface, making it difficult for a manual operator to keep the tilted angle consistent during the procedure. EUNSUNG-1017, 1:51-61. In order to avoid this “tilted angle” problem, a POSITA would have been motivated to adopt Mercier’s handpiece design with a “rotation inducing mechanism.” EUNSUNG-1017, 10:66-11:15 (“Indeed, the hand tool 1 is devised to be operated **orthogonally** with respect to the skin surface 3 being treated, thereby making operating and handling of the device much easier throughout the entire duration of the treatment than what is possible with some of the hand tools known in the art which are devised to be operated at a tilted angle with respect to the skin surface 3. Therefore, the present invention allows for a more uniform skin abrasion pattern throughout the duration of the treatment, and because the hand tool 1 is devised to be operated **orthogonally** to the skin surface 3 to be removed, the present invention also provides axisymmetrical abrasion patterns, and more particularly a circular abrasion pattern, similar to a circular ‘rubbing’ effect, which

is also very advantageous. Moreover, the evacuating means 23 are designed to optimize the vacuum stability of the system 2 over extended periods of time.”).

205. Third, as explained by Mercier, another problem with traditional handpiece design is that it tends to mark the skin surface with deep cavities, a phenomenon commonly known as “pitting” or “skin stabbing.” EUNSUNG-1017, 1:65-2:14. In order to avoid this “skin stabbing” problem, a POSITA would have been motivated to adopt Mercier’s handpiece design with a “rotation inducing means.” EUNSUNG-1017, 11:61-12:15 (“Hence, the various rotation-inducing means 37 of the present invention, as explained hereinabove, combine their effect to provide several distinct advantages to the whole system 2. Firstly, great stability of the projected abrasive stream 5 is achieved through particle rotation around the central axis of the abrasive stream 5. Furthermore, the rotation of the particles creates a homogeneous sweeping action in the manner of a generally rotational rubbing motion at the surface 3 of the skin. This second effect reduces the non-desirable ‘skin stabbing’ effect common to the orthogonal surface powder projection systems known in the art. Moreover, desirable abrasive stream stability is further enhanced by the fact that a whirlpool ordered and generally peripheral unobstructed motion of powder particles exit the work zone tip area, as explained hereinabove. Such a centrifugal induced rotational geometry powder exit flow results in a highly desirable minimal collision occurrence with the incoming

abrasive stream 5 projected from the projection head 33. As a result of the above-discussed, both the efficiency of the treatment of the skin surface 3 and the efficiency of the evacuation of the abrasive stream 5 are increased compared to the devices known in the prior art.”).

206. Fourth, as explained by Mercier, Mercier’s handpiece design is also advantageous because it enables a controlled and adjustable removal of the skin surface. EUNSUNG-1017, 10:42-61 (“Firstly, the hand tool 1 according to the present invention enables **a controlled and adjustable removal of superficial skin surface 3** by the projection of an abrasive stream 5 onto the skin surface 3 to be removed, as explained hereinabove. Indeed, the working principle of the hand tool 1 and of the different regulators 47, 49, 61 of the different components of the dermabrasion system 2 enable to provide a substantially homogeneous, stable, controlled, and adjustable removal of skin surface 3, in that a given velocity and pattern for the abrasive stream 5 may be selected by the operator of the present invention. For example, the removably interchangeable projection nozzles 97 enable to vary the parameters of the treatment carried out by the abrasive stream 5 being projected, depending on the particular needs of the treatment as required by the hand tool 1. Therefore, the present invention enables for a wide range of skin abrasions, ranging from a light abrasion where the outermost layers of the epidermis are removed, to a much deeper abrasion where the dermis is involved.

This ability to provide a wide range of skin abrasion depths and patterns is very advantageous.”). Thus, a POSITA would have been motivated to adopt Mercier’s handpiece design in order to achieve a more controlled and adjustable removal.

207. Finally, a POSITA would have been motivated to adopt Mercier’s handpiece design because it is easy to assemble, easy to use, and easy to maintain. EUNSUNG-1017, 12:16-23 (“Finally, the present invention is also advantageous in that the hand tool 1 is **easy to assemble, easy to use, and easy to maintain**, as explained hereinabove. Indeed, most of the components of the present invention are removably mounted to one another, thereby making assembling, cleaning, replacement, etc. of the components very easy. Furthermore, the ergonomic design of the hand tool 1 also provides a more comfortable and easier handling and operating thereof.”).

208. A POSITA would have had a reasonable expectation of success in such a combination. As discussed above, both Karasiuk-Palmer and Mercier are directed to a microdermabrasion device with a handpiece for applying a fluid treatment solution to a treatment site and a vacuum for collecting waste during microdermabrasion. EUNSUNG-1004, Abstract, [0013]-[0015], FIG. 6; EUNSUNG-1017, Abstract. Replacement of Karasiuk-Palmer’s handpiece (e.g., Karasiuk’s device 10) with Mercier’s handpiece (e.g., Mercier’s hand tool 1) reflects a simple substitution of a known element for another to obtain predictable

results—allowing easier operation and avoiding the “skin stabbing” and “half-moon” issues. This replacement would also reflect the use of a known technique to improve similar devices in the same way. *Id.*

209. Alternatively, in Karasiuk-Palmer-Mercier, Karasiuk-Palmer’s handpiece (e.g., Karasiuk’s device 10) would be modified based on Mercier’s handpiece (e.g., Mercier’s hand tool 1) so that an evacuating channel is extended inside Karasiuk’s handle 12 alongside Karasiuk’s tube 14 so that Karasiuk’s vacuum port 18b is located at proximal end 14a of Karasiuk’s tube 14. EUNSUNG-1017, FIGS. 2 and 4. In this way, both the supply conduit (e.g., Karasiuk’s tube 14 or collectively Palmer’s second tubing means 30, Karasiuk’s T joint 76’, and Karasiuk’s tube 14) and the waste conduit (e.g., Karasiuk’s “vacuum line between device 10 and vacuum source 40” or collectively Karasiuk’s vacuum line 42, second vacuum line 44, vacuum line 46) are connected to the proximal end of the handpiece (e.g., Karasiuk’s device 10). *Id.* A POSITA would have been motivated to make this modification because it allows bundling the supply conduit and waste conduit together, allowing easier handling by the operator.

210. A POSITA would have had a reasonable expectation of success in making such a modification. Both Karasiuk-Palmer and Mercier are directed to a microdermabrasion device with a handpiece for applying a fluid treatment solution to a treatment site and a vacuum for collecting waste during microdermabrasion.

EUNSUNG-1004, Abstract, [0013]-[0015], FIG. 6; EUNSUNG-1017, Abstract. A POSITA would have viewed moving Karasiuk's vacuum port 18b to the proximal end of the handpiece as a simple modification that would reflect the use of a known technique to improve similar devices in the same way. For example, Greenberg also discloses a similar microdermabrasion device with a handpiece for applying a fluid treatment solution to a treatment site and a vacuum for collecting waste during microdermabrasion, where each of the supply conduit and the waste conduit connects to a corresponding connector along a proximal end of the handpiece assembly. EUNSUNG-1006, FIGS. 1-6.

211. Alternatively or in addition, locating Karasiuk's vacuum port 18b on a proximal end of the handpiece assembly would have been obvious to try. A POSITA would have recognized a finite number of identified, predictable locations to locate Karasiuk's vacuum port 18b: at a proximal end of the handpiece assembly (similar to Mercier's FIG. 4), at a middle point between the proximal end and the distal end (similar to Karasiuk's FIG. 1), or at a distal end of the handpiece assembly. A POSITA would have had "good reason to pursue the known options," and thus, locating Karasiuk's vacuum port 18b at a proximal end of the handpiece assembly would have been obvious to try.

212. Alternatively or in addition, locating Karasiuk's vacuum port 18b at a proximal end of the handpiece assembly would have been an obvious design

choice because it is merely the rearrangement of parts without any “difference in function” or “unexpected results.” As evidenced by Mercier, locating Karasiuk’s vacuum port 18b at a proximal end of the handpiece assembly yields expected results without altering the function of the Karasiuk-Palmer system, and thus would have been “an obvious matter of design choice within the skill of the art.”

2. Claim 9

[9] The system of claim 1, wherein each of the supply conduit and the waste conduit connects to a corresponding connector along a proximal end of the handpiece assembly.

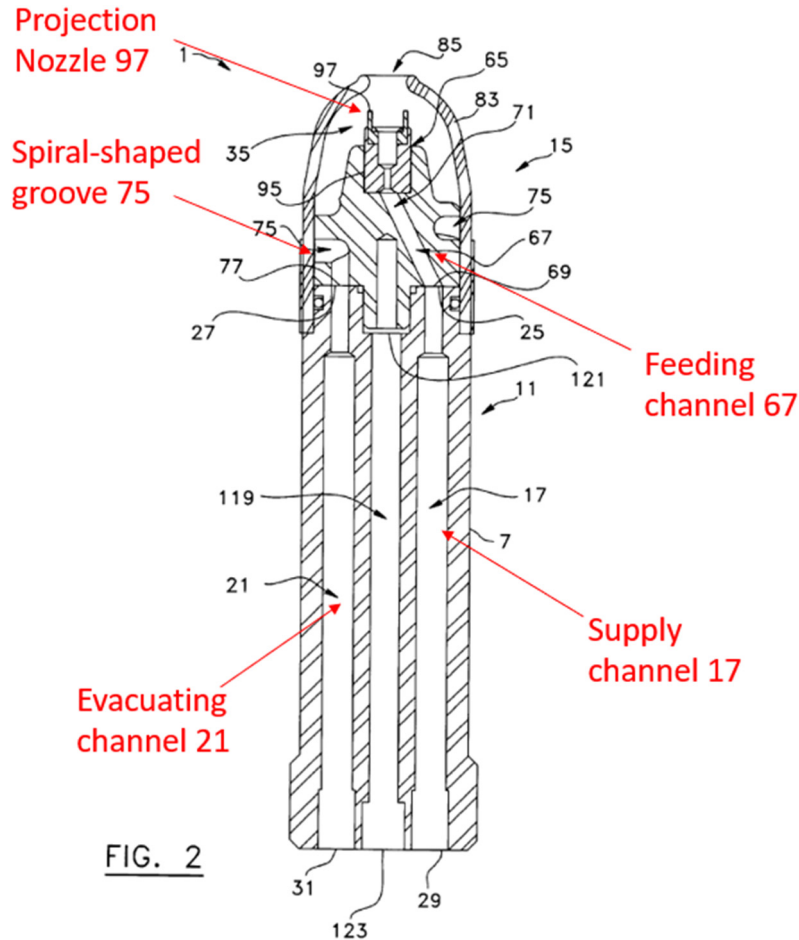
213. It is my opinion that Karasiuk-Palmer-Mercier renders obvious that each of the supply conduit and the waste conduit connects to a corresponding connector along a proximal end of the handpiece assembly. As discussed in Section XI, Karasiuk-Palmer-Mercier renders obvious claim 9 for the same reasons as discussed regarding Karasiuk-Palmer. Karasiuk-Palmer-Mercier further renders obvious [9] based on Mercier’s teachings.

214. In Karasiuk-Palmer-Mercier, Karasiuk-Palmer’s handpiece (e.g., Karasiuk’s device 10) would be replaced by Mercier’s handpiece (e.g., Mercier’s hand tool 1). Specifically, Mercier’s supply channel 17 would be connected to a supply conduit (e.g., Karasiuk’s tube 14 or collectively Palmer’s second tubing means 30, Karasiuk’s T joint 76’, and Karasiuk’s tube 14) and Mercier’s evacuating channel 21 would be connected to a waste conduit (e.g., Karasiuk’s

“vacuum line between device 10 and vacuum source 40” or collectively Karasiuk’s vacuum line 42, second vacuum line 44, vacuum line 46). EUNSUNG-1017, 4:56-61.

215. As shown in FIG. 2, Mercier’s supply channel 17 has a connector (e.g., second extremity 29) along a proximal end of the handpiece assembly, and Mercier’s evacuating channel 21 has a connector (e.g., second extremity 31) along a proximal end of the handpiece assembly. EUNSUNG-1017, FIG. 2. Mercier further discloses that “the second extremities 29, 31 of the supply and evacuating channels 17, 21 are preferably provided with **push-in connectors 62**, as better shown in FIG. 2, so as to facilitate connection of the flexible tubes 43, 55.” EUNSUNG-1017, 5:66-6:3; FIG. 6.

216. Thus, in Karasiuk-Palmer-Mercier, a POSITA would have understood and found obvious that each of the supply conduit and the waste conduit connects to a corresponding connector along a proximal end of the handpiece assembly (e.g., Mercier’s hand tool 1). EUNSUNG-1017, 4:56-61, 5:66-6:3, FIG. 2.



Mercier, FIG. 2 (annotated)

217. Alternatively, as discussed above in Section XIII.1, Karasiuk-Palmer's handpiece (e.g., Karasiuk's device 10) would be modified based on Mercier's handpiece (e.g., Mercier's hand tool 1) so that an evacuating channel is extended inside Karasiuk's handle 12 alongside Karasiuk's tube 14 so that Karasiuk's vacuum port 18b is located at proximal end 14a of Karasiuk's tube 14. EUNSUNG-1017, FIG. 2. In this way, both the supply conduit (e.g., Karasiuk's tube 14 or collectively Palmer's second tubing means 30, Karasiuk's T joint 76', and Karasiuk's tube 14) and the waste conduit (e.g., Karasiuk's "vacuum line

between device 10 and vacuum source 40” or collectively Karasiuk’s vacuum line 42, second vacuum line 44, vacuum line 46) are connected to the proximal end of the handpiece (e.g., Karasiuk’s device 10). *Id.* A POSITA would have been motivated to make this modification because it allows bundling the supply conduit and waste conduit together, allowing easier handling by the operator. Indeed, a POSITA would have understood or found obvious that having one general entry/exit location for conduits extending from a microdermabrasion handpiece would have offered the operator convenience during operation in only having to keep track of one set of bundled conduits extending from the handpiece, rather than two. In Karasiuk’s design, the waste conduit extends from a different location and in a different direction than the supply conduit, which makes it more difficult for an operator to keep track of the conduits during operation and makes it more likely that the movement of the handpiece would cause one of the supply or waste conduits to become tangled or inadvertently get caught on the patient or another object in the treatment area. A POSITA would have viewed these aspects of Karasiuk’s design to be disadvantageous relative to Mercier’s design in terms of allowing the operator to manipulate the handpiece without interference between the waste/supply conduits and objects in the treatment area. Based on these disadvantages and consistent with Mercier’s design, a POSITA would have been motivated and would have found it obvious to modify Karasiuk’s design to have

the waste conduit extend from the proximal end of the handpiece such that it extends from the same end of the handpiece in the same direction as the supply conduit and can be bundled with the supply conduit in a manner that is less likely to result in interference with other objects during operation.

XIV. [GROUND 1D]: Karasiuk-Palmer-Wunsch

1. Karasiuk-Palmer-Wunsch

218. It is my opinion that a POSITA would have been motivated to combine Karasiuk, Palmer, and Wunsch with a reasonable expectation of success. In the Karasiuk-Palmer-Wunsch combination (“Karasiuk-Palmer-Wunsch”), Karasiuk-Palmer’s system would have been modified so that Palmer’s liquid solution coupling and selector means 16 is replaced with Wunsch’s manifold selector and sequencer-timer. Specifically, each of Palmer’s containers (e.g., Palmer’s reservoirs 12₁-12₆) is connected via a corresponding supply tube 16 to Wunsch’s solution manifold selector 17, which is connected via dispensing tube 18 to Karasiuk’s tube 14. EUNSUNG-1020, 5:56-6:48, FIG. 1.

219. In the combination, Karasiuk’s vacuum source would be used to pump treatment solutions from Palmer’s multiple fluid containers and collect waste/debris. EUNSUNG-1004, [0020], [0056], [0064]-[0066]. Instead of being connected to single reservoir 70, Karasiuk’s tube 14 (e.g., upstream of breather line 76) would replace, or be connected to, Wunsch’s dispensing tube 18 to achieve

benefits resulting from selection of different treatment solutions. *Id.* In the resulting system, the vacuum source performs pumping the treatment solution and removing waste/debris, according to Karasiuk. *Id.*; EUNSUNG-1004, [0020], [0056], [0064]-[0066].

220. Wunsch discloses 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. Karasiuk recognizes desirability of using multiple types of skin treatment solutions during microdermabrasion. EUNSUNG-1004, [0024], [0047], [0061]. Therefore, the Karasiuk-Palmer-Wunsch system would have used Wunsch's manifold selector to *sequentially* deliver different skin treatment solutions—for example, a first container holding an antioxidant formulation (e.g., vitamin) and a second container holding a hydrating formulation (e.g., lotion). Section XI.1; 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.”).

221. Karasiuk-Palmer-Wunsch renders obvious the use of Wunsch’s manifold for the same reasons discussed regarding obviousness of using a manifold discussed for Karasiuk-Palmer. *see* Section XI.

222. A POSITA also would have been motivated to employ Wunsch’s manifold selector and sequencer-timer for several reasons. First, Wunsch’s manifold selector can be automatically controlled by the sequencer-timer to allow automatic dispensing of different treatment fluids. EUNSUNG-1020, 3:43-68, 4:11-17, 4:47-60. Wunsch discloses that “an accurate method for sequentially metering several different medications” is desirable because manual selection (e.g., via Palmer’s liquid solution coupling and selector means 16) is limited in that an operator must attend to the manual switching and the flushing of the system between different treatment fluids. EUNSUNG-1020, 2:10-13, 2:33-49. Based on this disclosure, a POSITA would have understood that manual selection is both cumbersome and prone to error, and would have been motivated to adopt Wunsch’s automatic control to provide added convenience and help avoid mis-selection by the user.

223. Second, a POSITA would have been motivated to adopt Wunsch’s manifold selector because it allows flushing of the manifold using the Keep Open Base Solution (TKO) between different treatment fluids to avoid cross-

contamination between two treatment fluids. EUNSUNG-1020, 2:33-49, 3:6-13, 8:6-9 (“thereby preventing intermixing of solutions”); EUNSUNG-1005, 1:54-68 (avoiding contamination).

224. Third, a POSITA would have been motivated to adopt Wunsch’s manifold selector because it allows easy replacement of the disposable manifold between patients, avoiding cross-contamination between patients and avoiding the need to clean and sterilize the manifold between uses. EUNSUNG-1020, 1:65-2:9; 2:50-59, 4:40-45, 6:27-38, 8:10-16; EUNSUNG-1005, 1:54-68 (avoiding contamination).

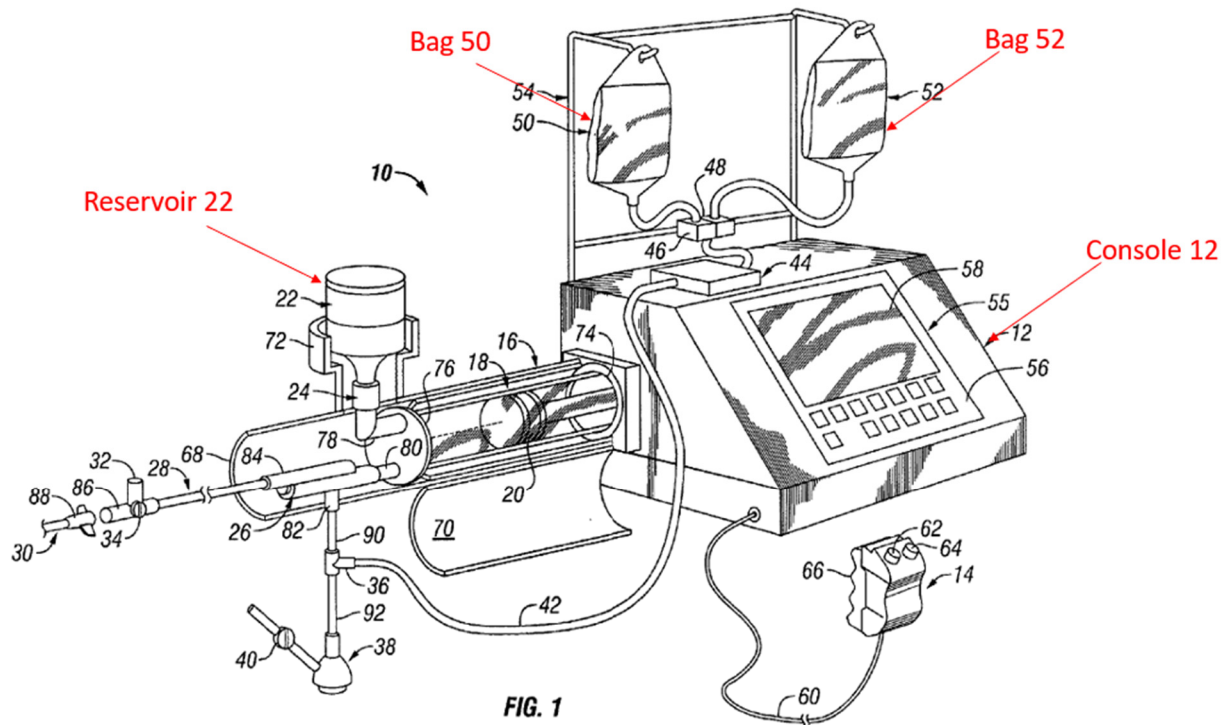
225. Additionally, a POSITA would have been motivated and found it obvious to place (1) multiple containers (as taught by Palmer), (2) Wunsch’s manifold selector and sequencer-timer, and (3) handheld device 10, collection reservoir 50, vacuum source 40, and other relevant components (as taught by Karasiuk) in a modular structure (e.g., Palmer’s mobile cart 170) for known benefits, such as increased portability and organization. Palmer recognizes that “[b]y providing the reservoir storage means 32 in the form of modular single-shelf racks, a high degree of flexibility is provided.” EUNSUNG-1005, 9:63-10:2, FIGS. 11A-11C. Indeed, such a modular configuration for medical devices was well-known before the Critical Date.

226. 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].

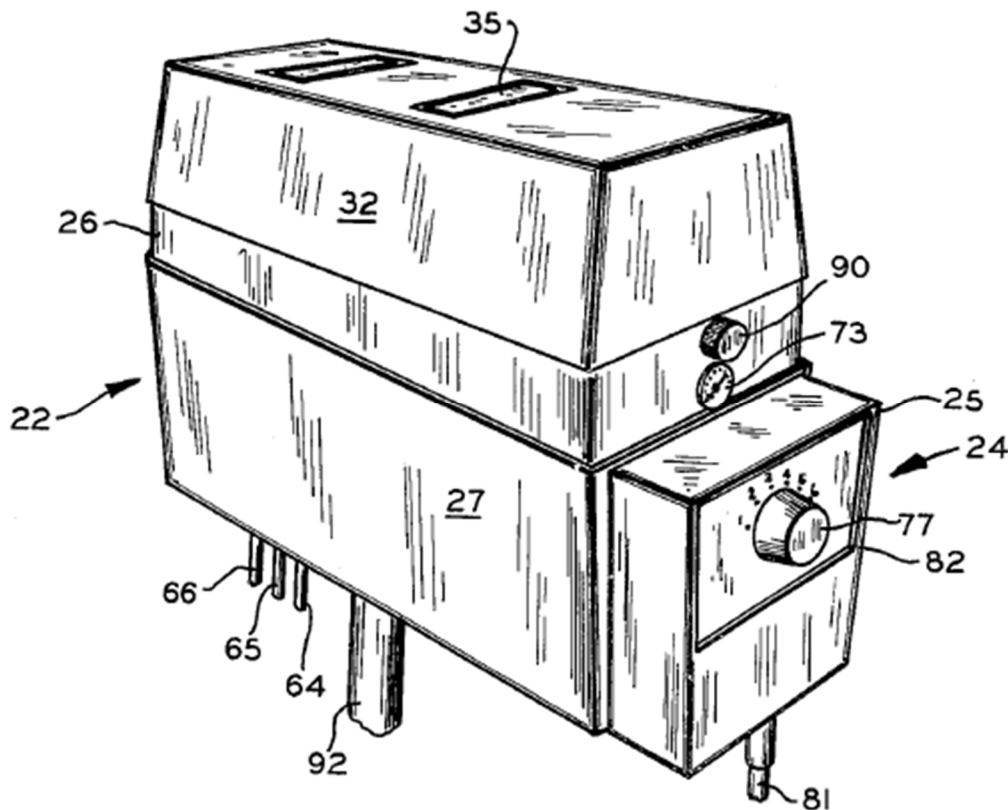


Duchon, FIG. 1 (annotated)

227. 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

228. 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.

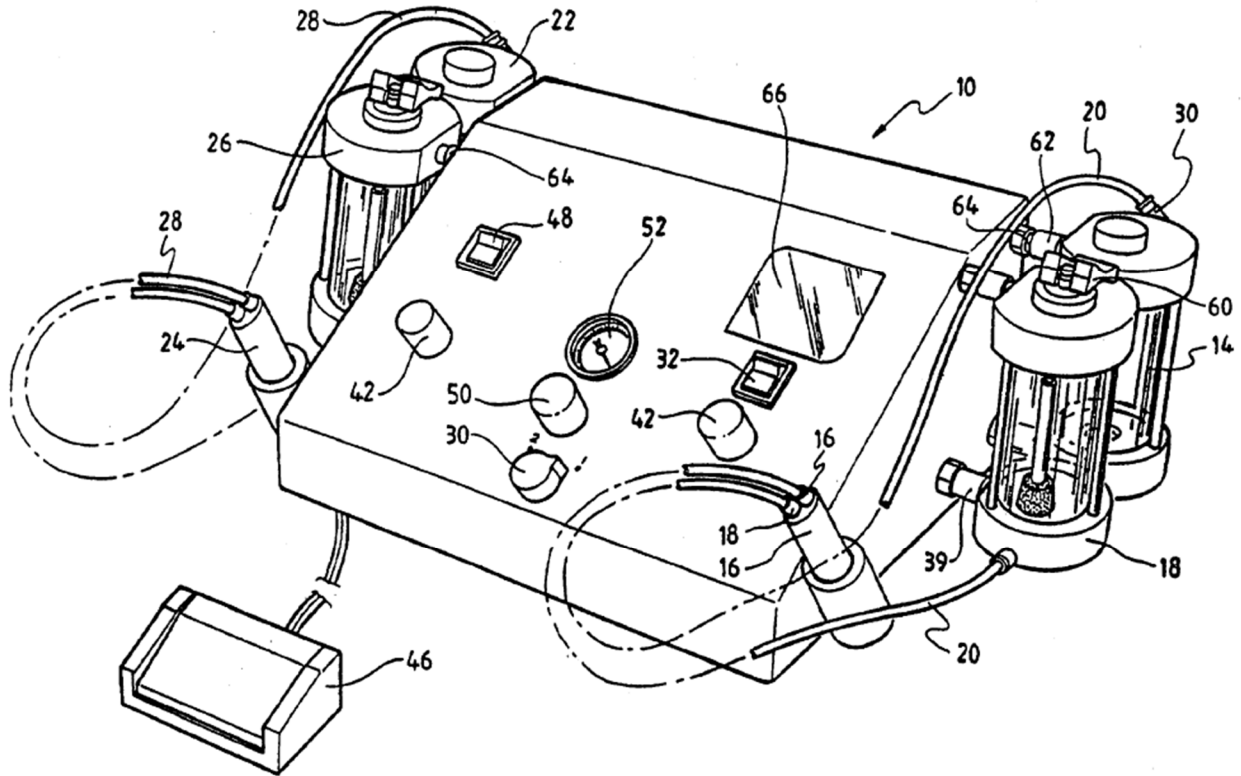
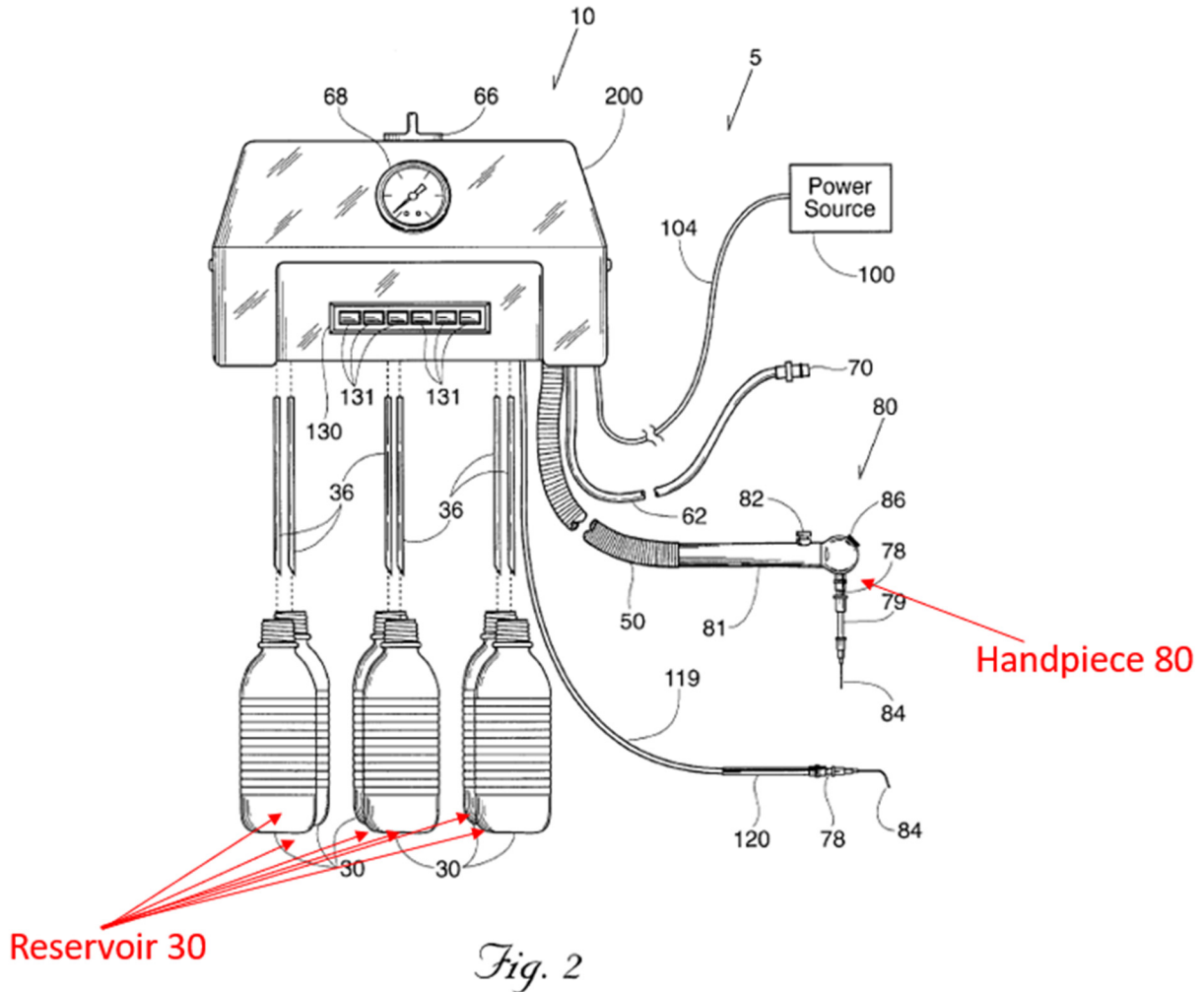


FIG 1

Greenberg, FIG. 1

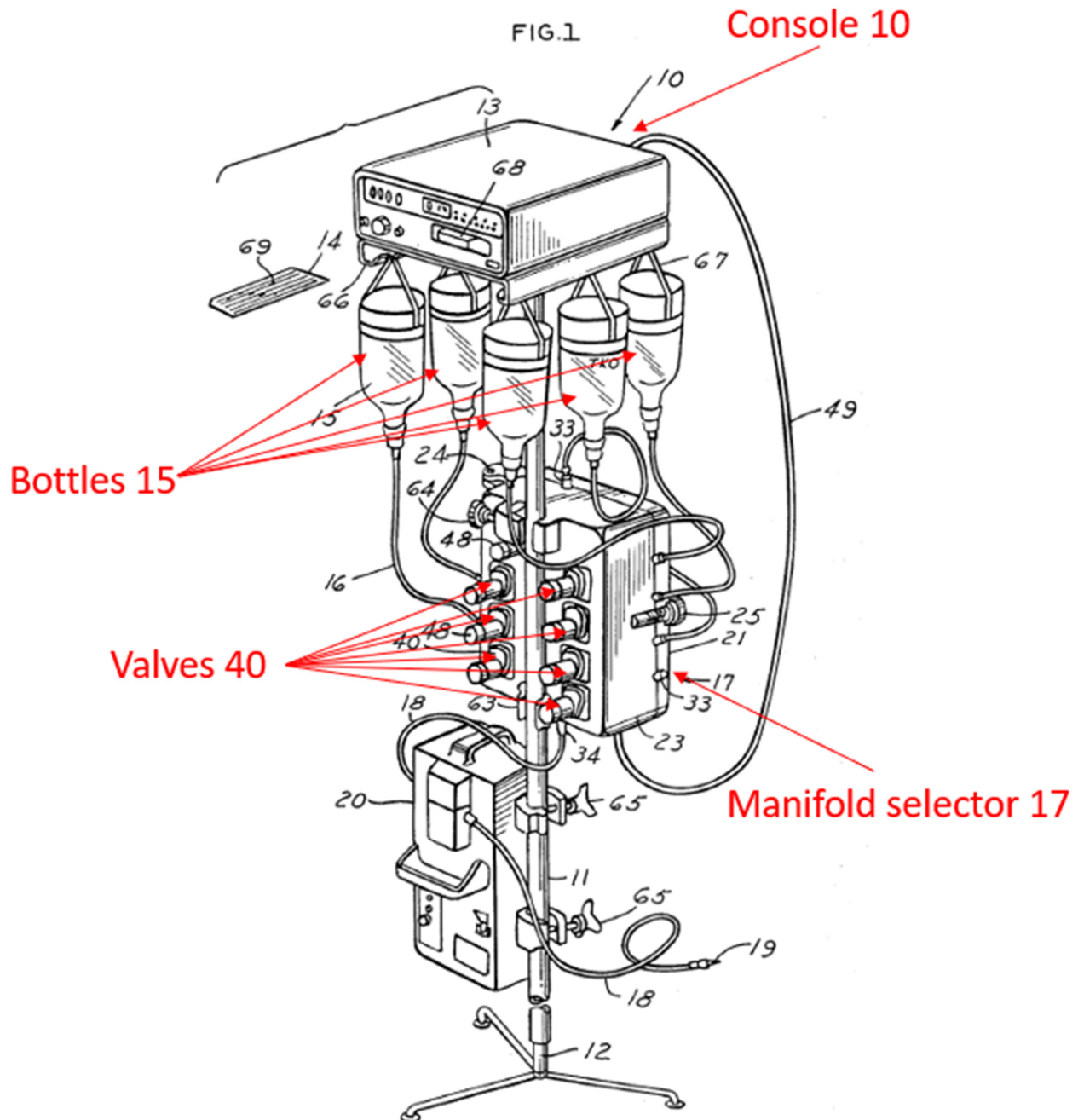
229. As another example, Pond discloses a fluid dispensing assembly that can be used to deliver the desired fluid from a plurality of releasable fluid containers (e.g., reservoirs 30) to the handpiece (e.g., handpiece 80). EUNSUNG-1007, Abstract, 2:1-21, 4:41-67.



Pond, FIG. 2 (annotated)

230. 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)

231. A POSITA would have replaced Palmer's liquid solution coupling

and selector means 16 with Wunsch's manifold selector and sequencer-timer with a reasonable expectation of success. Both Palmer's liquid solution coupling and selector means 16 and Wunsch's manifold selector are used to allow selected delivery of different treatment fluids. EUNSUNG-1005, 8:22-53 ("For example, when the knob is rotated so that the pointer 78 indicates the indicia designated '6,' the outlet passage 76 communicates with the inlet passage 74 which opens into the inlet port 22₆ which is coupled to the solution 34₆ contained in the reservoir 12₆."); EUNSUNG-1020, Abstract, 7:39-56, 8:17-26, FIGS. 1-4. While Wunsch's system is used for intravenous delivery, a POSITA would have understood that Wunsch's manifold selector and sequencer-timer are equally applicable to Karasiuk's topical delivery. Wunsch discloses in detail how to set up the manifold selector, which contains a plurality of valves 40 controlled by motor means (e.g., reversible electric motor 48 or solenoids 59) and how to use the sequencer-timer to control the valves (e.g., by sending positive voltages). EUNSUNG-1020, Abstract, 3:16-42, 5:25-35, 7:17-56, 8:17-9:5, 9:36-10:64, FIGS. 1-4. Replacing Palmer's liquid solution coupling and selector means 16 with Wunsch's manifold selector and sequencer-timer constitutes a simple substitution of one known element for another to obtain predictable results—automated sequential delivery of multiple treatment fluids.

2. Claim 1

[1.pre] A system for performing a skin treatment procedure, the system comprising:

232. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious a system for performing a skin treatment procedure. *See* Section XI (Ground 1A).

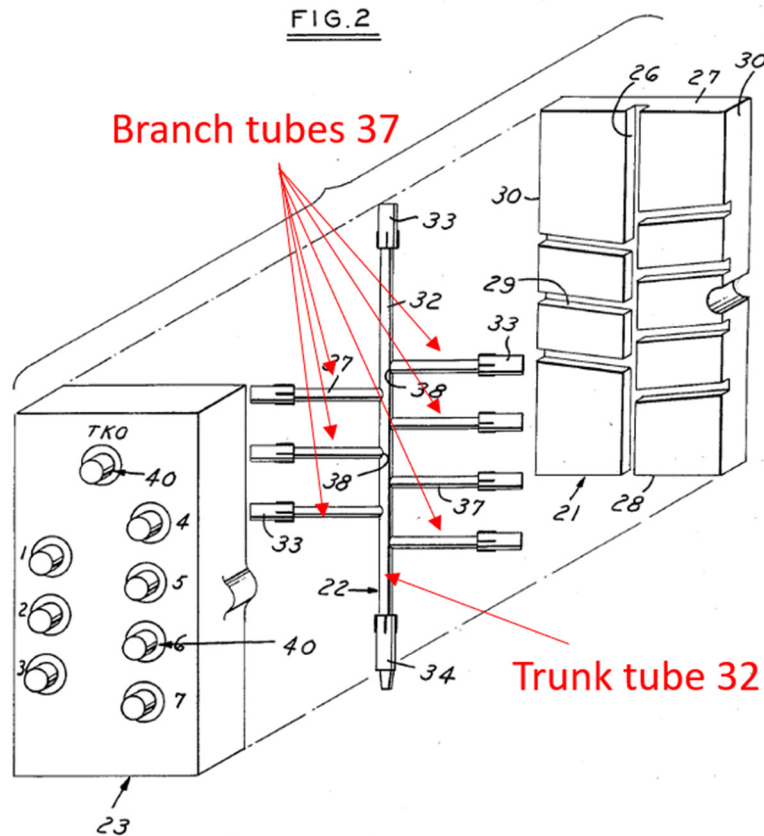
[1.1] a console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;

233. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious a console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid. *See* Section XI (Ground 1A).

234. Regarding “console,” Wunsch further illustrates in FIG. 1 that the system is mounted on a support standard post 12. EUNSUNG-1020, 5:18-24, 9:19-29, FIG. 1. A POSITA would have been motivated and found it obvious to place (1) multiple containers (as taught by Palmer), (2) Wunsch’s manifold selector and sequencer-timer, and (3) handheld device 10, collection reservoir 50, vacuum source 40, and other relevant components (as taught by Karasiuk) in a modular structure (e.g., Palmer’s mobile cart 170) for known benefits, such as increased portability and organization. Palmer recognizes that “[b]y providing the reservoir

storage means 32 in the form of modular single-shelf racks, a high degree of flexibility is provided.” EUNSUNG-1005, 9:63-10:2, FIGS. 11A-11C. Indeed, such a modular configuration for medical devices was well-known before the Critical Date.

235. Regarding “manifold,” as discussed above in Section XIV.1, in Karasiuk-Palmer-Wunsch, Karasiuk-Palmer’s system would have been modified so that Palmer’s liquid solution coupling and selector means 16 is replaced with Wunsch’s manifold selector and sequencer-timer. As discussed above in Section X.5, Wunsch discloses that manifold selector 17 includes a manifold 22 including a trunk tube 32 and a plurality of branch tubes 37, each of which connecting to one of the plurality of bottles 15. EUNSUNG-1020, 3:23-42, 6:61-7:16.



Wunsch, FIG. 2 (annotated)

236. In operation, by activating an individual valve 40, the user can selectively connect a chosen bottle 15 to the trunk tube 32 for delivery.

EUNSUNG-1020, 3:23-42 (“Upon operation of an electric motor means, such as a reversible motor, or a solenoid is adapted to retract the valve element of the valve for a predetermined period to permit the passage of intravenous fluid in one of the branches or through the inlet of the manifold for a predetermined period.”), 7:17-56.

[1.2] a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;

237. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject. *See* Section XI (Ground 1A).

[1.3] a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly;

238. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly. *See* Section XI (Ground 1A).

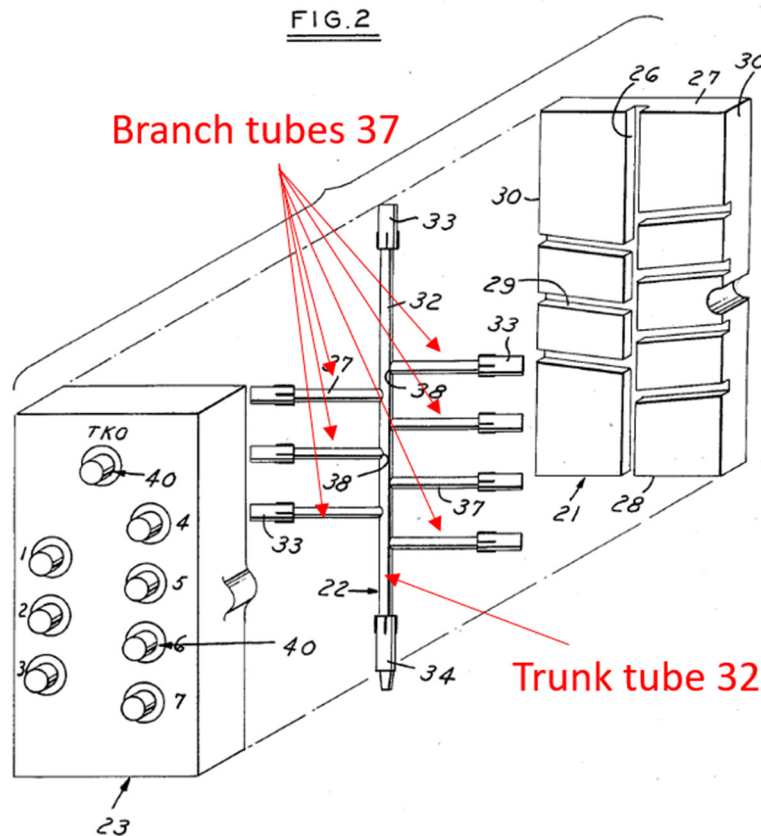
[1.4] wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; and

239. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit. *See* Section XI (Ground 1A).

240. As discussed above in Section XIV.1, in Karasiuk-Palmer-Wunsch, Karasiuk-Palmer's system would have been modified so that Palmer's liquid solution coupling and selector means 16 is replaced with Wunsch's manifold selector and sequencer-timer.

241. Regarding "manifold," as discussed above in Section X.5, Wunsch

discloses that manifold selector 17 includes a manifold 22 including a trunk tube 32 and a plurality of branch tubes 37, each of which connecting to one of the plurality of bottles 15. EUNSUNG-1020, 3:23-42, 6:61-7:16.



Wunsch, FIG. 2 (annotated)

242. In operation, by activating an individual valve 40, the user can selectively connect a chosen bottle 15 to the trunk tube 32 for delivery.

EUNSUNG-1020, 3:23-42 (“Upon operation of an electric motor means, such as a reversible motor, or a solenoid is adapted to retract the valve element of the valve for a predetermined period to permit the passage of intravenous fluid in one of the branches or through the inlet of the manifold for a predetermined period.”), 7:17-

56.

[1.5] a vacuum source;

243. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious a vacuum source. *See* Section XI (Ground 1A).

[1.6] a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source; and

244. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source. *See* Section XI (Ground 1A).

[1.7] wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly; and

245. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly. *See* Section XI (Ground 1A).

246. In Karasiuk-Palmer-Wunsch, the sequencer-timer 13 is a controlled sequencer that allows users to program arbitrary on-off sequences on eight to ten independent channels by means of pencil marks applied to tracks 69 upon the

program card 14, FIG. 1. EUNSUNG-1020, 9:43-68. To program the on-off timing sequence, the operator simply darkens the desired On intervals on the card 14 upon the respective tracks 69 with a soft No. 2 pencil. EUNSUNG-1020, 10:18-25.

Timing information represented by pencil marks on the programming card 14 along the respective tracks 69 is read by photosensors or a suitable card reader.

EUNSUNG-1020, 10:1-8. On the output end, the programmer timer 13 provides positive voltages to activate the switches in the manifold selector 17 in compliance with the information programmed on the program input card 14. EUNSUNG-1020, 9:62-68. By programming Wunsch's sequencer-timer 13, a user can select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly.

[1.8] wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

247. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit. See Section XI (Ground 1A).

3. Claim 4

[4] The system of claim 1, wherein the first fluid container or the at least a second fluid container is releasably coupled to the manifold.

248. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that the first fluid container or the at least a second fluid container is releasably coupled to the manifold. *See* Section XI (Ground 1A).

249. Wunsch further discloses that manifold 22 is releasably coupled to the containers via supply tubes 16. EUNSUNG-1020, 4:41-46, 6:13-17, 6:27-38 (“to permit removal and replacement of tubing manifold 22”), 8:10-16 (“the tubing manifold may be simply disconnected from the supply tubes 16 and removed from the manifold selector 17”). Wunsch discloses that the releasable connection allows replacement of the manifold 22 when a new patient is to be hooked up to the manifold selector 17. EUNSUNG-1020, 8:10-16. In view of this disclosure, because the treatment fluids for one patient may differ from the those for the next patient, a POSITA would have understood and found obvious that the first fluid container or the at least a second fluid container is releasably coupled to the manifold via supply tubes 16.

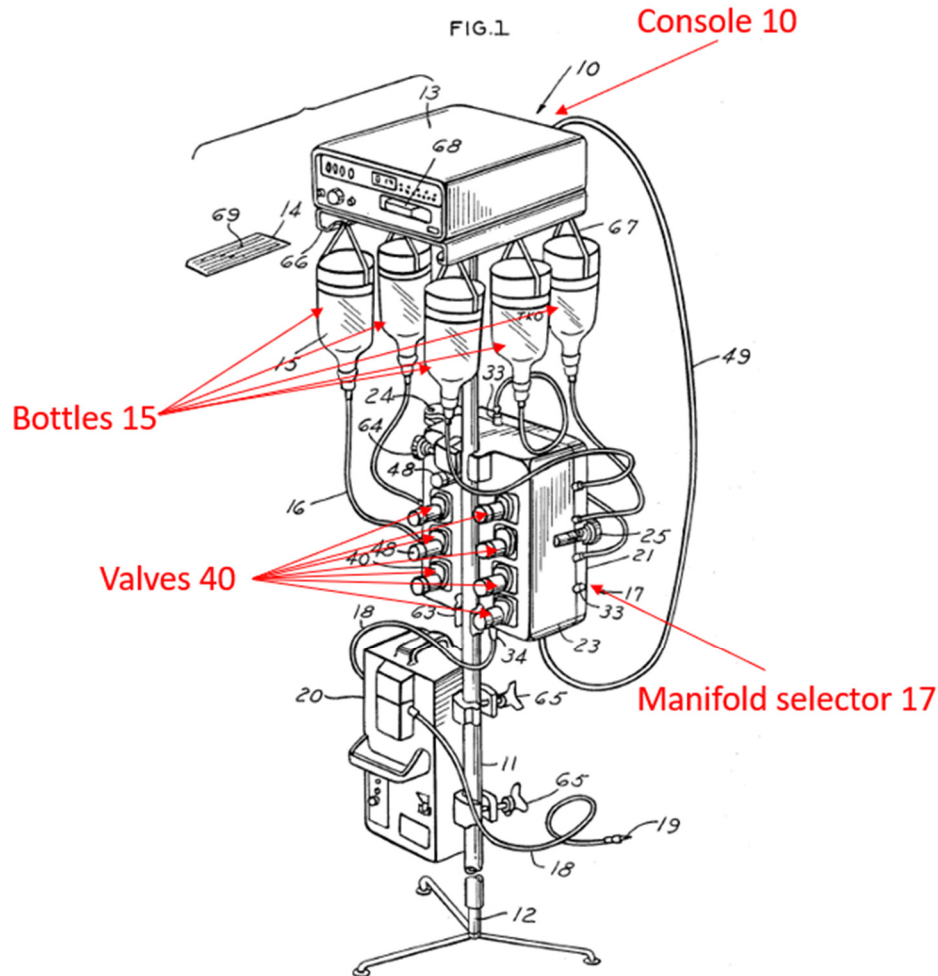
4. Claim 5

[5] The system of claim 1, wherein the manifold is configured to be placed in fluid communication with at least four fluid containers.

250. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that the manifold is configured to be placed in fluid communication with at least four

fluid containers. *See* Section XI (Ground 1A).

251. Wunsch discloses “up to eight solutions may be accommodated by a single manifold selector 17.” EUNGSUNG-1020, 8:17-26. Wunsch also shows in FIG. 1 five different bottles 15 (*fluid containers*). EUNSUNG-1020, FIG. 1.



Wunsch, FIG. 1 (annotated)

5. Claim 6

[6] The system of claim 1, wherein treatment materials from the first fluid container and at least the second fluid container are delivered to the supply conduit sequentially or simultaneously.

252. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that treatment materials from the first fluid container and at least the second fluid container are delivered to the supply conduit sequentially or simultaneously. *See* Section XI (Ground 1A).

253. Wunsch discloses 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. Karasiuk recognizes desirability of using multiple types of skin treatment solutions during microdermabrasion. EUNSUNG-1004, [0024], [0047], [0061]. Therefore, the Karasiuk-Palmer-Wunsch system would have used Wunsch's manifold selector to *sequentially* deliver different skin treatment solutions—for example, a first container holding an antioxidant formulation (e.g., vitamin) and a second container holding a hydrating formulation (e.g., lotion). Section XI.1; 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.”).

254. As shown in FIG. 1, Wunsch’s 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. Each of the valves 40 has an open position in which fluid is permitted to flow from the supply tubes 16 into the dispensing tube 18 and a closed position in which the branch tube 37 or trunk 32 is pinched off to prevent fluid flow therethrough. EUNSUNG-1020, 7:52-56. Wunsch further discloses exemplary reversible electric motors 48, FIG. 3, or solenoids 59, FIG. 4, for individually controlling the operation of the respective valves 40. EUNSUNG-1020, 3:16-22, 6:24-26, FIGS. 3-4. These motors are connected to and controlled by a sequencer-timer 13. EUNSUNG-1020, 5:25-35, 8:27-9:5. 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.

255. Thus, a POSITA would have understood and found obvious that in Karasiuk-Palmer-Wunsch, treatment materials from the first fluid container and at least the second fluid container are delivered to the supply conduit sequentially or simultaneously.

6. Claim 7

[7] The system of claim 1, wherein the console is movable.

256. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that the console is movable. *See* Section XI (Ground 1A).

257. Regarding “console,” Wunsch further illustrates in FIG. 1 that the system is mounted on a support standard post 12. EUNSUNG-1020, 5:18-24, 9:19-29, FIG. 1. A POSITA would have understood and found obvious that Wunsch’s console is also movable.

7. Claim 8

[8] The system of claim 1, wherein the tip of the handpiece assembly is configured to exfoliate skin tissue as the handpiece assembly is moved relative to a skin surface of a subject.

258. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that the tip of the handpiece assembly is configured to exfoliate skin tissue as the handpiece assembly is moved relative to a skin surface of a subject. *See* Section XI (Ground 1A).

8. Claim 9

[9] The system of claim 1, wherein each of the supply conduit and the waste conduit connects to a corresponding connector along a proximal end of the handpiece assembly.

259. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that each of the supply conduit and the waste conduit connects to a corresponding connector along a proximal end of the handpiece assembly. *See* Section XI (Ground 1A).

9. Claim 10

[10] The system of claim 1, wherein the manifold of the console is configured to be placed in fluid communication with a container comprising an antimicrobial fluid or other disinfecting agent for periodic flushing of the manifold.

260. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that the manifold of the console is configured to be placed in fluid communication with a container comprising an antimicrobial fluid or other disinfecting agent for periodic flushing of the manifold. *See* Section XI (Ground 1A).

10. Claim 11

[11.pre] A system for performing a skin treatment procedure, the system comprising:

261. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious a system for performing a skin treatment procedure. *See* [1.pre].

[11.1] a manifold in fluid communication with at least two fluid containers, each of the at least two fluid containers being configured to contain a treatment material, wherein the treatment material comprises a liquid;

262. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious a manifold in fluid communication with at least two fluid containers, each of the at least two fluid containers being configured to contain a treatment material, wherein the treatment material comprises a liquid. *See* [1.1].

[11.2] a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;

263. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious a handpiece assembly comprising a tip, the tip being configured to contact a skin

surface of a subject. *See* [1.2].

[11.3] a supply conduit placing the manifold in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to secure to the handpiece assembly;

264. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious a supply conduit placing the manifold in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to secure to the handpiece assembly. *See* [1.3]. As discussed in [1.3], in Karasiuk-Palmer-Wunsch, a POSITA would have understood and found obvious that a distal end of the supply conduit is configured to “couple” to the handpiece assembly. For the same reasons, a POSITA would have understood and found obvious that a distal end of the supply conduit is configured to “secure” to the handpiece assembly.³

EUNSUNG-1004, [0044] (“Handle 12 is annular or tubular, providing a passageway 12a through which tube 14 is extended”), [0045] (“The distal end 14b of tube 14 is connected to cannula 16, Cannula 16 is adapted to be fixed to handle 12”), [0059] (“Tube 14 extends from the proximal end of the microdermabrasion device 10”), FIGS. 1A and 6. A POSITA would have understood and found obvious that for the supply conduit to deliver treatment solutions to the handpiece, it needs to be securely connected to and in fluid communication with the handpiece. *Id.*

³ The specification of the ’052 patent does not use the term “secure.”

[11.4] a vacuum source; and

265. See [1.5].

[11.5] a waste conduit in fluid communication with the handpiece assembly to remove waste from a skin surface of a subject during a procedure, wherein the waste conduit is operatively coupled to the vacuum source;

266. See [1.6].

[11.6] wherein the manifold is configured to control a flow of treatment material from each of the at least two fluid containers through the supply conduit;

267. See [1.4].

[11.7] wherein the system is configured to permit a user to select the fluid container from which treatment material is delivered to the supply conduit.

268. See [1.7].

11. Claim 12

[12] The system of claim 11, further comprising a user input device for selecting a treatment material to be passed through the supply conduit to the handpiece assembly.

269. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious a user input device for selecting a treatment material to be passed through the supply conduit to the handpiece assembly. Wunsch discloses a user input device in the form of a sequencer-timer 13. In Karasiuk-Palmer-Wunsch, the sequencer-timer 13 is a controlled sequencer that allows users to program arbitrary on-off sequences on eight to ten independent channels by means of pencil marks applied to tracks 69 upon the program card 14, FIG. 1. EUNSUNG-1020, 9:43-68. To program the on-off timing sequence, the operator simply darkens the desired On intervals on the

card 14 upon the respective tracks 69 with a soft No. 2 pencil. EUNSUNG-1020, 10:18-25. Timing information represented by pencil marks on the programming card 14 along the respective tracks 69 is read by photosensors or a suitable card reader. EUNSUNG-1020, 10:1-8. On the output end, the programmer timer 13 provides positive voltages to activate the switches in the manifold selector 17 in compliance with the information programmed on the program input card 14. EUNSUNG-1020, 9:62-68. Thus, a POSITA would have understood and found obvious that Wunsch's sequencer-timer 13 is a user input device for selecting a treatment material to be passed through the supply conduit to the handpiece assembly.

12. Claim 15

[15] The system of claim 11, wherein the at least two fluid containers is releasably coupled to the manifold.

270. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that the at least two fluid containers is releasably coupled to the manifold. *See* [4].

13. Claim 16

[16] The system of claim 11, wherein the tip of the handpiece assembly is configured to exfoliate skin tissue as the handpiece assembly is moved relative to a skin surface of a subject.

271. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that the tip of the handpiece assembly is configured to exfoliate skin tissue as the handpiece assembly is moved relative to a skin surface of a subject. *See* [8].

14. Claim 17

[17] The system of claim 11, wherein the manifold is configured to be placed in fluid communication with a container comprising an antimicrobial fluid or other disinfecting agent for periodic flushing of the manifold.

272. It is my opinion that Karasiuk-Palmer-Wunsch renders obvious that the manifold is configured to be placed in fluid communication with a container comprising an antimicrobial fluid or other disinfecting agent for periodic flushing of the manifold. *See* [10].

XV. [GROUND 1E]: Karasiuk-Palmer-Wunsch-Trueba

1. Karasiuk-Palmer-Wunsch-Trueba

273. It is my opinion that a POSITA would have been motivated to combine Karasiuk, Palmer, Wunsch and Trueba with a reasonable expectation of success. In Karasiuk-Palmer-Wunsch-Trueba, Karasiuk-Palmer-Wunsch is further modified by Trueba based on Trueba's teachings of computer control and display. While Wunsch discloses a sequencer-timer in the form of a controlled sequencer that reads instructions from a marked up program card 14, a POSITA would have understood that computer technologies have progressed significantly since 1982, and would have replaced Wunsch's sequencer-timer with Trueba's computer with a touch screen to provide a more convenient user-interface, added clarity, and added programming capabilities. Through this modification, Karasiuk-Palmer-Wunsch-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.

274. Further, for the same reasons discussed in Section XII regarding Karasiuk-Palmer-Trueba, a POSITA would have been motivated to modify Karasiuk-Palmer-Wunsch to include Trueba’s computer control and display with a reasonable expectation of success. Comparing to Karasiuk-Palmer-Trueba, Wunsch provides added expectation of success because Wunsch discloses in detail how to set up the manifold selector, which contains a plurality of valves 40 controlled by motor means (e.g., reversible electric motor 48 or solenoids 59) and how to use the sequencer-timer to control the valves (e.g., by sending positive voltages). EUNSUNG-1020, Abstract, 3:16-42, 5:25-35, 7:17-56, 8:17-9:5, 9:36-10:64, FIGS. 1-4. Replacing Wunsch’s sequencer-timer 13 with Trueba’s computer with a touch screen constitutes a simple substitution of one known element for another to obtain predictable results—a more convenient user-interface, added clarity, and added programming capabilities.

275. For the same reasons discussed in Section XII, Karasiuk-Palmer-Wunsch-Trueba’s system includes a display indicating which solution is being delivered, and that the display can be a user input device (e.g., Trueba’s touch screen 105) to select a flow of fluids from containers to the handpiece. EUNSUNG-1008, 11:40-12:8, FIG. 3.

276. For the same reasons discussed in Section XII, a POSITA would have

understood and found it obvious to place the touch screen in the console to provide added flexibility, organization, and portability. EUNSUNG-1008, FIG. 3.

2. Claims 1, 4-12, 15-17

277. As discussed in Section XIV above, Karasiuk-Palmer-Wunsch-Trueba renders obvious claims 1, 4-12, 15-17 for the same reasons as discussed regarding Karasiuk-Palmer-Wunsch.

3. Claim 2

[2] The system of claim 1, wherein the console comprises a display, wherein the display comprises a user input device to facilitate controlling a flow of treatment materials from the first fluid container or the at least a second fluid container to the handpiece assembly.

278. It is my opinion that Karasiuk-Palmer-Wunsch-Trueba renders obvious that the console comprises a display, wherein the display comprises a user input device to facilitate controlling a flow of treatment materials from the first fluid container or the at least a second fluid container to the handpiece assembly. As discussed in Section XIV, Karasiuk-Palmer-Wunsch-Trueba renders obvious claim 1 for the same reasons as discussed regarding Karasiuk-Palmer-Wunsch. Karasiuk-Palmer-Wunsch-Trueba further renders obvious [2] based on Trueba's teachings.

279. As discussed in Section XV.1, Karasiuk-Palmer-Wunsch-Trueba's system includes a display indicating which solution is being delivered, and that the display can be a user input device (e.g., Trueba's touch screen 105) that can be

used to select a flow of fluids from containers to the handpiece. EUNSUNG-1008, 11:40-12:8, FIG. 3. Further, as discussed in Section XV.1, a POSITA would have understood and found it obvious to place the touch screen in the console to provide added flexibility, organization, and portability. EUNSUNG-1008, FIG. 3. Thus, in Karasiuk-Palmer-Wunsch-Trueba, a POSITA would have understood and found obvious that the console comprises a display (e.g., Trueba's display 105), wherein the display comprises a user input device (e.g., Trueba's touch screen 105) to facilitate controlling a flow of treatment materials from the first fluid container or the at least a second fluid container to the handpiece assembly.

4. Claim 3

[3] The system of claim 2, wherein the user input device comprises a touch screen.

280. It is my opinion that Karasiuk-Palmer-Wunsch-Trueba renders obvious that the user input device comprises a touch screen. As discussed in Section XV.1, Karasiuk-Palmer-Trueba's user input device includes a touch screen. EUNSUNG-1008, 11:40-12:8, FIG. 3.

5. Claim 6

[6] The system of claim 1, wherein treatment materials from the first fluid container and at least the second fluid container are delivered to the supply conduit sequentially or simultaneously.

281. It is my opinion that Karasiuk-Palmer-Wunsch-Trueba renders obvious that treatment materials from the first fluid container and at least the

second fluid container are delivered to the supply conduit sequentially or simultaneously. As discussed in Section XIV, Karasiuk-Palmer-Wunsch-Trueba renders obvious claim 6 for the same reasons as discussed regarding Karasiuk-Palmer-Wunsch.

282. Karasiuk-Palmer-Wunsch-Trueba further renders obvious [6] based on Trueba's teachings. EUNSUNG-1008, 3:4-8, 5:18-6:9, 6:10-16, 11:4-34, 12:2-9. As discussed in Section XV.1, Karasiuk-Palmer-Wunsch-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-Wunsch to provide a more convenient user-interface, added clarity, and added programming capabilities.

6. Claim 12

[12] The system of claim 11, further comprising a user input device for selecting a treatment material to be passed through the supply conduit to the handpiece assembly.

283. It is my opinion that Karasiuk-Palmer-Wunsch-Trueba renders obvious a user input device for selecting a treatment material to be passed through the supply conduit to the handpiece assembly. *See* [2].

284. As discussed in Section XIV, Karasiuk-Palmer-Wunsch-Trueba

renders obvious claim 12 for the same reasons as discussed regarding Karasiuk-Palmer-Wunsch. Karasiuk-Palmer-Wunsch-Trueba further renders obvious [12] based on Trueba's teachings.

285. As discussed in Section XV.1, Karasiuk-Palmer-Wunsch-Trueba's system includes a display indicating which solution is being delivered, and that the display can be a user input device (e.g., Trueba's touch screen 105) to select a flow of fluids from containers to the handpiece. EUNSUNG-1008, 11:40-12:8, FIG. 3. Thus, in Karasiuk-Palmer-Wunsch-Trueba, a POSITA would have understood and found obvious that the system includes a user input device (e.g., Trueba's touch screen 105) for selecting a treatment material to be passed through the supply conduit to the handpiece assembly.

7. Claim 13

13. The system of claim 11, wherein the system comprises a display, wherein the display comprises a user input device to facilitate controlling a flow of treatment materials from the at least two fluid containers.

286. It is my opinion that Karasiuk-Palmer-Wunsch-Trueba renders obvious that the system comprises a display, wherein the display comprises a user input device to facilitate controlling a flow of treatment materials from the at least two fluid containers. *See* [2].

8. Claim 14

[14] The system of claim 13, wherein the user input device comprises a touch

screen.

287. It is my opinion that Karasiuk-Palmer-Wunsch-Trueba renders obvious that the user input device comprises a touch screen. *See* [3].

XVI. [GROUND 1F]: Karasiuk-Palmer-Wunsch-Mercier

1. Karasiuk-Palmer-Wunsch-Mercier

288. It is my opinion that a POSITA would have been motivated to combine Karasiuk, Palmer, Wunsch, and Mercier with a reasonable expectation of success. For the same reasons discussed above regarding Karasiuk-Palmer-Mercier, a POSITA would have combined Karasiuk-Palmer-Wunsch with Mercier. *See* Section XIII.1.

289. As discussed in Section XIII.1, in Karasiuk-Palmer-Wunsch-Mercier, Karasiuk-Palmer-Wunsch's handpiece (e.g., Karasiuk's device 10) would be replaced by Mercier's handpiece (e.g., Mercier's hand tool 1). Specifically, as discussed in Section XIII.1, Mercier's supply channel 17 would be connected to a supply conduit (e.g., Karasiuk's tube 14 or collectively Palmer's second tubing means 30, Karasiuk's T joint 76', and Karasiuk's tube 14) and Mercier's evacuating channel 21 would be connected to a waste conduit (e.g., Karasiuk's "vacuum line between device 10 and vacuum source 40" or collectively Karasiuk's vacuum line 42, second vacuum line 44, vacuum line 46). EUNSUNG-1017, 4:56-61.

290. Alternatively, As discussed in Section XIII.1, in Karasiuk-Palmer-

Wunsch-Mercier, Karasiuk-Palmer-Wunsch's handpiece (e.g., Karasiuk's device 10) would be modified based on Mercier's handpiece (e.g., Mercier's hand tool 1) so that an evacuating channel is extended inside Karasiuk's handle 12 alongside Karasiuk's tube 14 so that Karasiuk's vacuum port 18b is located at proximal end 14a of Karasiuk's tube 14. EUNSUNG-1017, FIG. 2. In this way, both the supply conduit (e.g., Karasiuk's tube 14 or collectively Palmer's second tubing means 30, Karasiuk's T joint 76', and Karasiuk's tube 14) and the waste conduit (e.g., Karasiuk's "vacuum line between device 10 and vacuum source 40" or collectively Karasiuk's vacuum line 42, second vacuum line 44, vacuum line 46) are connected to the proximal end of the handpiece (e.g., Karasiuk's device 10). *Id.* A POSITA would have been motivated to make this modification because it allows bundling the supply conduit and waste conduit together, allowing easier handling by the operator.

2. Claim 9

[9] The system of claim 1, wherein each of the supply conduit and the waste conduit connects to a corresponding connector along a proximal end of the handpiece assembly.

291. It is my opinion that Karasiuk-Palmer-Wunsch-Mercier renders obvious that each of the supply conduit and the waste conduit connects to a corresponding connector along a proximal end of the handpiece assembly. As discussed in Section XIV, Karasiuk-Palmer-Wunsch-Mercier renders obvious

claim 9 for the same reasons as discussed regarding Karasiuk-Palmer-Wunsch.

Karasiuk-Palmer-Wunsch-Mercier further renders obvious [9] based on Mercier's teachings. *See* Section XIII.

XVII. CONCLUSION

292. In conclusion, I find the claims of the '052 patent addressed herein to be rendered obvious in their entirety, based upon the prior art combinations of Karasiuk-Palmer, Karasiuk-Palmer-Trueba, Karasiuk-Palmer-Mercier, Karasiuk-Palmer-Wunsch, Karasiuk-Palmer-Wunsch-Trueba, and Karasiuk-Palmer-Wunsch-Mercier, and the supporting prior art of these combinations.

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

294. 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.

295. 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.

296. 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: 01/09/2025

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 Sun Valley Ice Center, Sun Valley, Idaho Ice Sheet Maintenance and Refrigeration Systems MANUFACTURING ENGINEER American Medical Optics, Irvine, California Intraocular and Contact Lenses		
	Education Master of Engineering, Bioengineering, Biomaterials & Product Design, University of Utah Bachelor of Science, Materials Science & Engineering, Biomaterials/Fabrication University of Utah Mechanical Engineering / Premedicine, University of Michigan		
	Legal Experience Expert Witness - 13 cases total Patent Infringement / Invalidation / Breach of Confidentiality - 4 cases Personal Injury / Medical Malpractice - 9 cases		
	<i>(detailed history available upon request)</i> • 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 Explanted 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.
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- 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.
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- 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