UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NU MARK LLC,
Petitioner,

v.

FONTEM HOLDINGS 1 B.V.,
Patent Owner.

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Case No. **IPR2016-01707**
Patent No. **9,326,550**

DECLARATION OF RICHARD MEYST IN SUPPORT OF PATENT OWNER PRELIMINARY RESPONSE TO PETITION FOR *INTER PARTES* REVIEW

I, Richard Meyst, declare as follows:

Personal Background

1. I am currently the President and Chief Executive Officer of Fallbrook Engineering, Inc. I am an engineer and consultant in the field of electromechanical devices, including medical devices. A copy of my CV, which includes, among other things, my academic credentials and my employment history, is attached as Exhibit A.

2. I have been retained by Patent Owner Fontem Holdings 1 B.V. as an expert witness in the above-captioned proceeding. I am being compensated for the time I spend on this proceeding at a rate of $425 per hour. My field of expertise in this matter is electromechanical and medical devices. This Declaration is based upon my knowledge, skill, experience, training, and education in my field of expertise, and upon information reviewed in connection with my retention as an expert witness in this matter.

3. I received an M.S. (1972) and B.S. (1971) in mechanical engineering from the University of Wisconsin, Madison. My undergraduate academic work focused on design, manufacturing methods, fluid mechanics, and heat transfer. My graduate academic focus was on computer-based automatic controls of systems and my Master's thesis was on the concept development, design, fabrication, and

testing of a prototype bench-top implantable mechanical human heart. Additionally, I have participated in industry seminars and training programs covering design of experiments, statistical analysis, biocompatibility testing, sterilization method selection and validation, design of plastic parts, design for manufacturability, package design and testing, cellular therapy, and many others.

4. As an engineer, designer, consultant, program manager and entrepreneur at Fallbrook Engineering, Inc., I have been involved in the advanced design and development of a wide range of medical technology products for the healthcare industry for more than 25 years. Prior to 1989 when I became a partner in Fallbrook Engineering, I held various engineering and management positions at healthcare, medical device, and consumer product companies, including USCI (a division of CR Bard, Inc.), Fenwal (a division of Baxter Travenol Laboratories), Oak Communication, Imed Corp., a division of Warner Lambert, and Diatek Corp.

5. During my 40+ year professional career, I have focused on electromechanical devices and related technologies requiring expertise in design, fluid mechanics, thermodynamics, heat transfer, electronic power sources, circuit design and fabrication, sensors, manufacturing technologies, and other areas of engineering design and manufacturing methods. Based on my experience, I have developed extensive knowledge in medical product design and development, product prototyping, design verification and validation, production startup,

manufacturing engineering, risk analysis, and strategic planning. In addition to doing engineering work, my responsibilities have included running a medical design and development consulting firm which includes assembling and managing technical teams to develop new medical, consumer, industrial, and professional products.

6. I have also been a Principal Investigator on several NIH SBIR grants from the National Heart, Lung, and Blood Institute developing a device for the improved collection of Umbilical Cord Blood Stem Cells. I have served on the Board of Directors for the Society of Plastics Engineers/Medical Plastics Division and am a long time member. I am a member of the American Association of Blood Banks, the Association for the Advancement of Medical Instrumentation, the San Diego Regulatory Affairs Network, the American Association for Clinical Chemistry, and the American Filtration & Separation Society.

7. I have also been a long-time member of the Medical Device Steering Committee of BIOCOM, the largest regional life science association in the world. I was recently a juror in the annual Medical Design Excellence Awards competition, the premier awards program for the medical technology community, as well as a judge in the San Diego CONNECT capital competition for startup companies. I am also an experienced inventor and innovator. My inventions have been awarded 16 U.S. Patents, and I have applications pending. I have been an

invited speaker and have presented talks at numerous scientific and medical industry meetings. Exhibit A includes a list of my patents, publications and presentations, and professional associations.

8. I have also served as an independent technical expert witness or consultant relating to numerous intellectual property and patent litigations, product failure analyses, analyses of the use and misuse of various medical devices, development contract disputes, and medical product liability matters. A list of my expert assignments within the past four years appears in Exhibit A.

Items Reviewed

9. I have reviewed the specification, claims, and certain portions of the file history U.S. Patent No. 9,326,550 ("'550 Patent," Ex. 1001), the specification of U.S. Patent Appl. No. 12/226,819 ("'819 Application") as set forth in U.S. Patent Publ. No. 2009/0126745 ("'745 Publication," Ex. 1005), and the specification of U.S. Patent Appl. No. 13/754,521 as originally filed ("'521 Application," Ex. 1002). I have also reviewed the Petition for *Inter Partes* Review filed by Petitioner Nu Mark LLC in this matter (Paper 1; "Petition") and related exhibits, including the declaration of Petitioner's expert, Dr. John Collins ("Collins") (Ex. 1003). I have paid particular attention to the exhibits that are discussed in this declaration.

The '550 Patent's Priority Claim

10. It is my understanding that the '550 Patent issued on May 3, 2016, from U.S. Patent Appl. No. 14/720,288 ("'288 Application"). The '288 Application was a continuation of the '521 Application, which was filed on January 30, 2013, and which issued as U.S. Patent No. 9,370,205. The '521 Application was a continuation of the '819 Application, which published as the '745 Publication on May 21, 2009, and issued as U.S. Patent No. 8,375,957 on February 19, 2013.

11. It is my understanding that the '819 Application was a national phase entry of PCT Appl. No. PCT/CN07/001576 ("'576 Application"), which was filed in Chinese on May 15, 2007, and published as WO07/131450 (also in Chinese) on November 22, 2007. It is my understanding that as a national phase entry of the '576 Application, the '819 Application is understood to have the same filing date as the '576 Application.

12. It is my understanding that '288 Application, '521 Application, '819 Application, and '576 Application all claim priority to Chinese Patent Appl. No. 200620090805.0, filed May 16, 2006.

13. Throughout this declaration, I have used the specification of the '745 Publication (Ex. 1005) to evaluate written description of the '819 Application. I note that Petitioner and Collins also rely primarily on the '745 Publication (which they refer to as "Hon '745") to evaluate the disclosure of the '819 Application.

14. My understanding is that the figures in the '745 Publication are substantively identical to those in the '576 Application as published (WO07/131450, Ex. 2008). In the copy of the '745 Publication I have reviewed, the figures are blurry. The figures in the published version of the '576 Application are clearer. Therefore, when reproducing the '745 Publication figures herein, I have used the versions from WO07/131450 (Ex. 2008).

The '550 Patent Claims

15. The '550 Patent includes 24 claims, but it is my understanding that only claims 1-12 are being challenged by Petitioner in this proceeding. Claims 1-12 include one independent claim, which reads as follows:

> Claim 1: A vaporizing device comprising: an electronic cigarette including: a battery assembly comprising a tubular battery assembly housing having a first end and a second end, with a battery and a micro-controller unit electrically connected to a circuit board within the battery assembly housing; a first screw thread electrode on the first end of the battery assembly housing, with a first through hole at a center of the first screw thread electrode; an atomizer assembly comprising: a tubular atomizer assembly housing having a first end and a second end; an atomizer having a porous body, and a liquid supply in the tubular atomizer assembly housing; with the atomizer including a heater wire wound on a part of the porous body which is perpendicular to a longitudinal axis of the tubular atomizer

assembly housing; an airflow path through an opening in the atomizer to a suction nozzle at the second end of the tubular atomizer assembly housing; a second screw thread electrode on the second end of the atomizer assembly housing, with a second through hole at a center of the second screw thread electrode; and the battery assembly and the atomizer assembly mechanically connected to form the electronic cigarette by engagement of the first screw thread electrode with the second screw thread electrode, and with electricity conducted from the battery to the heater wire through the first and second screw thread electrodes for heating the heater wire.

'550 Patent (Ex. 1001), col. 4, l. 44 to col. 5, l. 7.

16. Claim 1 recites a vaporizing device comprising an electronic cigarette that includes a battery assembly and an atomizer assembly, wherein the atomizer assembly comprises a tubular atomizer assembly housing that contains an atomizer and a liquid supply. The battery and atomizer assemblies are mechanically and electrically connected via a first screwthread electrode on a first end of the battery assembly and a second screwthread electrode on a second end of the atomizer assembly.

Level of Ordinary Skill in the Art

17. To assess the level of ordinary skill in the art, I understand that one may consider such factors as: (1) educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4)

rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.

18. I understand that the relevant time for assessing the level of skill in the art is the earliest date of filing of an application that supports the claimed inventions. For the '550 Patent, this date is either May 15, 2007, the filing date of the '576 Application, or May 16, 2006, the filing date of the Chinese priority application. My opinion regarding the level of ordinary skill in the art is the same for either of these dates.

19. As used herein, a "person of ordinary skill in the art," "one skilled in the art," and the like refers to a person with a mechanical or electrical engineering degree, industrial design degree, or similar technical degree, or equivalent work experience, and 5-10 years of working in the area of electromechanical devices, including medical devices. This is similar to the definition of a person of ordinary skill in the art offered by Petitioner and Collins, but their definition only requires 3-5 years of work experience. Petition (Paper 1), p. 19; Collins (Ex. 1003), ¶18. However, it is my opinion that a person of ordinary skill in the art would have more work experience. My opinions set forth herein are the same under either definition.

Claim Construction

20. I understand that claim terms are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of the invention when read in the context of the specification and prosecution history unless a patentee sets out a different definition or clearly disavows claim scope. I also understand that in the context of a proceeding in front of the Board, a claim is given the broadest reasonable construction in light of the specification. I further understand that extrinsic evidence such as expert or inventor testimony, dictionaries, and learned treatises can help determine the meaning of claim terms, although that evidence is less significant than the claims, specification, and prosecution history.

21. It is also my understanding that claims are to be interpreted from the perspective of one of ordinary skill in the relevant art at the time of invention. My opinion regarding the level of ordinary skill in the art is set forth above.

22. I have reviewed the claims of the '550 Patent, and based on the claim language, specification, and extrinsic evidence, I describe my opinions below as to how a person of ordinary skill in the art at the time of the invention would have interpreted certain claim terms.

Liquid supply

23. Independent claim 1 of the '550 Patent recites a "liquid supply." The plain meaning of this term would be clear to a person of ordinary skill in the art, who would understand a "liquid supply" to simply refer to "a store for liquid."

24. The '550 Patent provides an example of a liquid supply in the form of a "cigarette liquid bottle (401)" containing "fiber (402)." The fiber contains cigarette liquid, and when the electronic cigarette is assembled, this liquid-soaked fiber lies against the atomizer and soaks the micro-porous ceramics inside the atomizer. '550 Patent (Ex. 1001), col. 2, ll. 48-53; col. 3, ll. 7-9. In this manner, the bottle and fiber provide a store for liquid to be vaporized by the atomizer.

25. Extrinsic evidence supports the construction of "liquid supply" as "a store for liquid." The Oxford American Dictionary defines the noun "supply" as "a stock, store, amount, etc., of something provided or obtainable (*a large supply of water; the gas supply*), and Random House Webster's Unabridged Dictionary defines it as "7. Something that is supplied: *The storm cut off our water supply*. 8. A quantity of something on hand or available, as for use, a stock or store: *Did you see our new supply of shirts?* 9. A provision, stock or store of food or other things necessary for maintenance…." Ex. 2002 at 1535; Ex. 2004 at 1912.

26. Based on the '550 Patent specification and on extrinsic evidence, it is my opinion that "liquid supply" means "a store for liquid."

Written description analysis

27. I understand an *inter partes* review will be instituted only if the Petitioner has shown a reasonable likelihood that a claim is unpatentable based on the cited prior art.

28. I understand that Petitioner has argued that claims 1-12 of the '550 Patent are unpatentable under (pre-AIA) 35 U.S.C. § 102 as anticipated by the '745 Publication, which as discussed above is the U.S. publication of the '819 Application. Petition (Paper 1), p. 17.

29. I understand that the Petition is based on the assertion that the '550 Patent is not entitled to priority to the '819 Application because the disclosure of the '819 Application does not meet the written description requirement of 35 U.S.C. § 112 for the '550 Patent claims. Specifically, the Petitioner argues that the '819 Application does not meet the written description requirement for claims reciting an electronic cigarette that does not explicitly include a separate cigarette bottle assembly. It is my understanding that if the '819 Application does in fact meet the written description requirement for the '550 Patent claims, then those claims cannot be anticipated by the '745 Publication.

30. In preparing and forming my opinions set forth herein, it is my understanding that a patent's specification must contain a written description of the claimed invention. I also understand that an adequate written description is

provided if the application reasonably conveys to one of ordinary skill in the art through express, implicit, or inherent disclosures that the inventor had possession of the claimed subject matter as of the relevant filing date. Finally, I understand that a priority claim to an earlier filed application requires written description not only in that earlier filed application, but also in any intervening applications.

31. I understand that if a patent application sets out problems in the prior art, the patent claims do not have to address all of those problems. I understand that the patent claims can address one or more problems so long as they satisfy the written description requirement.

32. I further understand that the use of "the invention" or "the present invention" can limit an application's written description, but is not limiting where other portions of the intrinsic evidence do not support applying the limitation to the entire invention.

33. After reviewing and analyzing the '550 Patent claims, the specification of the '819 Application (in the form of the '745 Publication), and the documents cited in the Petition, it is my opinion that the '819 Application would have reasonably conveyed to one of ordinary skill in the art at the time it was filed that the applicant had possession of an electronic cigarette comprising "a liquid supply in the tubular atomizer housing." I reached this conclusion based on my analysis as further described below.

34. As described above, Collins and I define a person of ordinary skill in the art slightly differently. My conclusions set forth herein regarding written description are the same under either of these definitions.

35. In forming my opinions, I have considered written description from the perspective of one of ordinary skill in the art as of May 15, 2007, the filing date of the '576 Application. My opinions would be the same from the perspective of one of ordinary skill in the art on May 16, 2006, the filing date of the Chinese priority application.

"Bottle-less" claims

36. As noted by Petitioner and Collins, the '550 Patent claims do not recite a "cigarette liquid bottle." Petition (Paper 1), pp. 52, 63; Collins (Ex. 1003), ¶84. Accordingly, Petitioner and Collins refer to the devices recited in the '550 Patent claims as "bottle-less" devices. Petition (Paper 1), p. 3; Collins (Ex. 1003), ¶84.

37. Collins incorrectly states that the '550 Patent claims do not recite "any similar structure for storing liquid." Collins (Ex. 1003), ¶84. As discussed above, "liquid supply" means a store for liquid, and as such includes a "structure for storing liquid." Similarly, "liquid absorbed in fiber material" also includes a "structure for storing liquid."

38. Petitioner and Collins argue that the '819 Application does not provide written description support for the so-called "bottle-less" claims of the '550 Patent because the '819 Application "uniformly describes the claimed invention as having three assemblies – a battery assembly, an atomizer assembly, and a cigarette bottle assembly." Collins (Ex. 1003), ¶¶89, 92; Petition (Paper 1), p. 4. As set forth below, I disagree with this conclusion.

A person of ordinary skill in the art would not understand the written description of the '819 Application to be limited to electronic cigarettes that include a separate cigarette bottle assembly

39. It is my understanding that a patentee is not required to include in their claims every advantage or feature described as significant or important in the specification. The '819 Application discloses a battery assembly and atomizer assembly configured to be electrically connected to one another via electrodes on their respective ends. This configuration constitutes an inventive component of the disclosed devices because it produces an electronic cigarette in which the individual assemblies can be attached and detached from one another, and also allows for easy recharging of the battery assembly. This aspect of the disclosed devices does not hinge on the presence of a separate cigarette bottle assembly. As such, one of ordinary skill in the art would understand that the written description of the '819 Application is not limited exclusively to electronic cigarettes containing

such an assembly, and that the "bottle-less" claims of the '550 Patent are therefore fully described by the '819 Application.

40. This would be particularly true in view of the '819 Application's explicit statement that the disclosed examples are not necessarily meant to restrict the scope of the invention, and that "[a]ny equivalent modification…made on the basis of the design spirit of this invention shall fall into the scope of protection of this invention." Hon '745 (Ex. 1005), ¶0043. In view of that statement, one of ordinary skill in the art would understand that the disclosed devices are not limited to only devices having cigarette bottle assemblies.

The '819 Application describes an electronic cigarette comprising a liquid supply in a tubular atomizer assembly housing

41. Independent claim 1 of the '550 Patent recites "a liquid supply in the tubular atomizer assembly housing." This is explicitly described in the '819 Application.

42. Annotated Figures 5A, 5B, and 12 of the '819 Application, below, show examples of the disclosed electronic cigarettes. These examples include a battery assembly that includes battery 203 located inside primary shell 211 (which corresponds to the battery assembly housing recited in the '550 Patent claims), and an atomizer assembly that includes atomizer 307 located inside secondary shell 306 (which corresponds to the atomizer assembly housing recited in the '550 Patent

claims). The battery and atomizer assemblies in Figures 5A, 5B, and 12 are electrically connected to one another via electrodes at the end of each assembly.

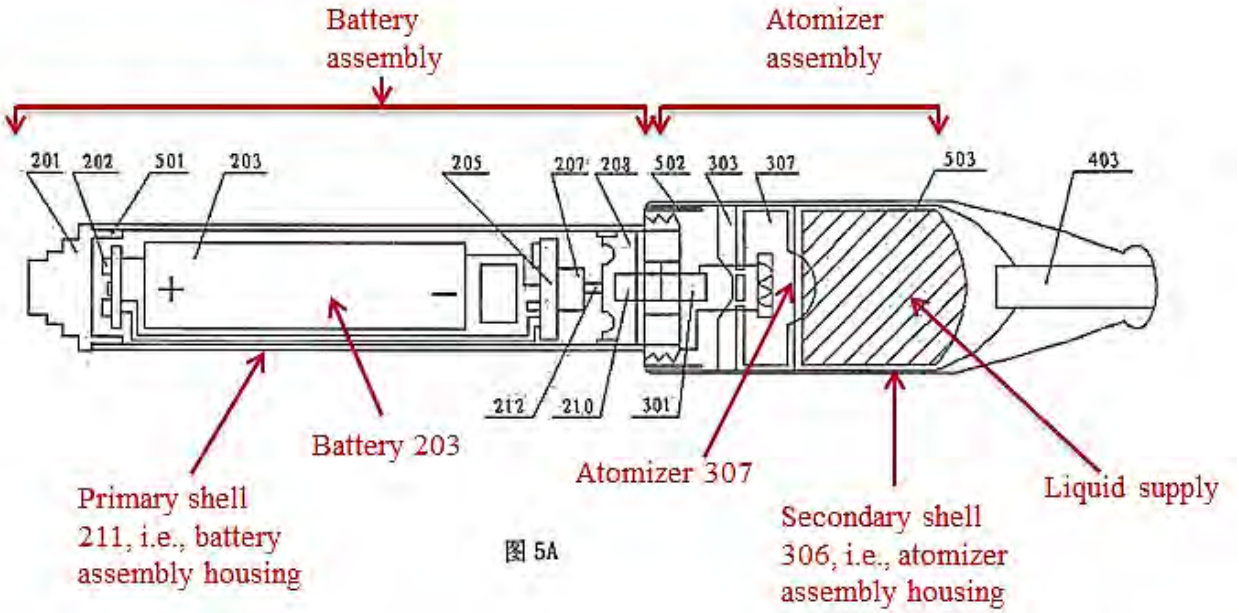


图 5A

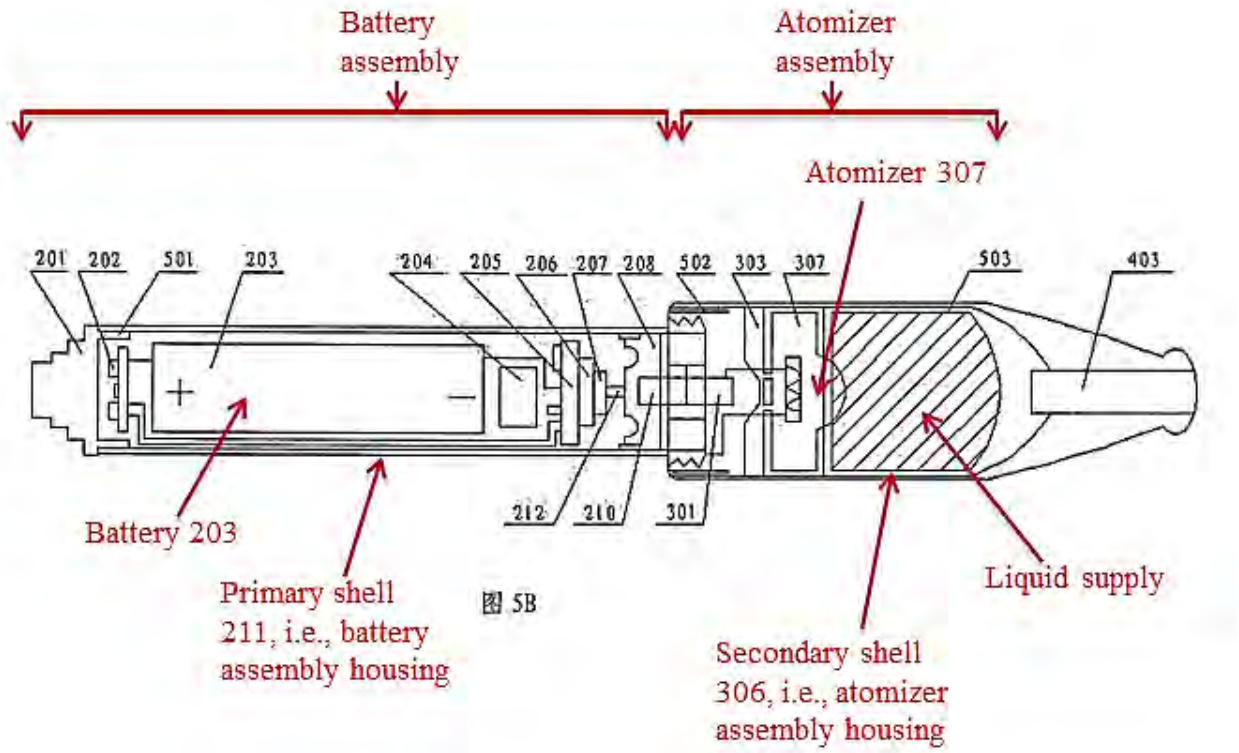
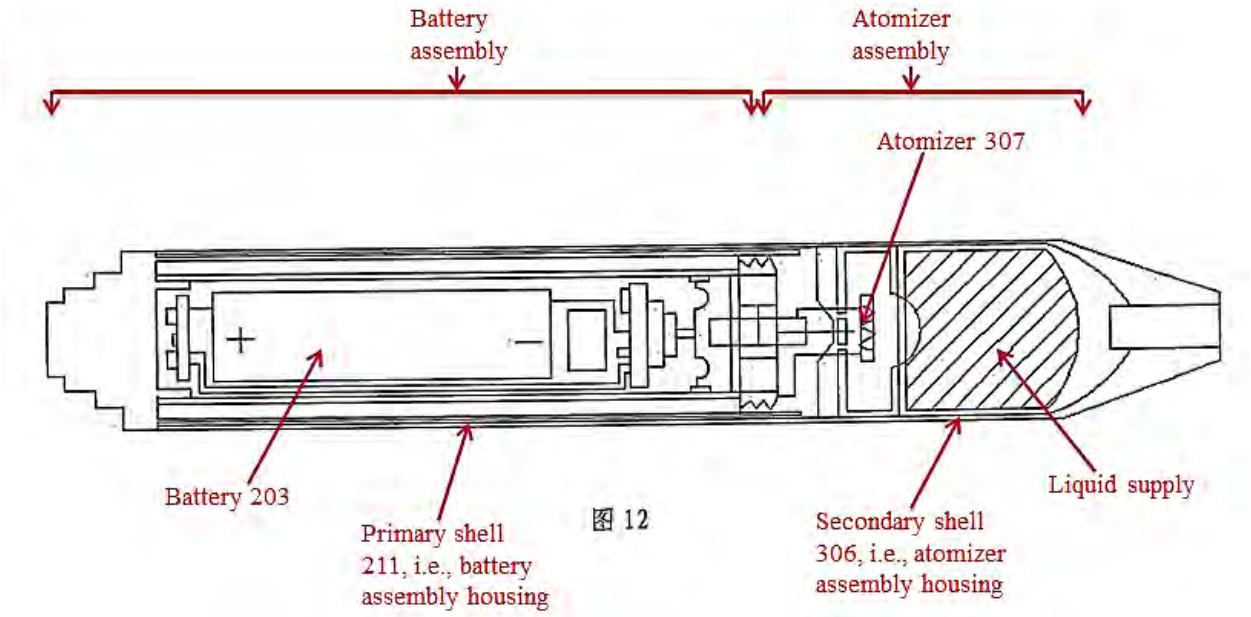


图 5B



43. In the fully assembled device of Figures 5A, 5B, and 12, a cigarette bottle assembly has been inserted into the atomizer assembly housing. '745 Publication (Ex. 1005), ¶¶0032, 0040. As illustrated in Figure 4 of the '819 Application, below, this cigarette bottle assembly includes fiber 402. '745 Publication (Ex. 1005), ¶0031. The fiber serves as a store for liquid to be vaporized by the atomizer, and as such constitutes a "liquid supply" as recited in the '550 Patent claims.

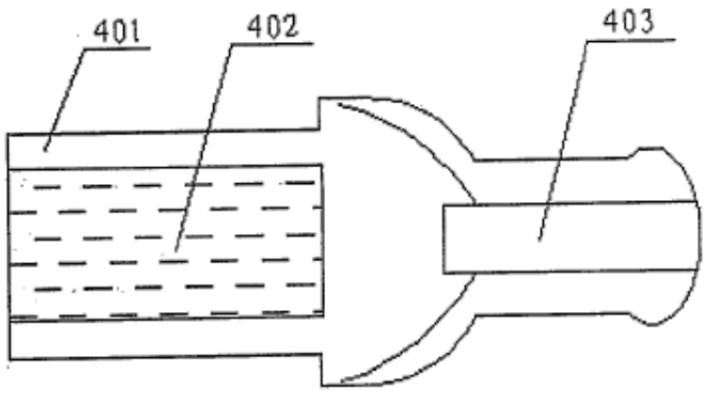


图 4

44. In the fully assembled device of Figures 5A, 5B, and 12, the bottle assembly is inserted such that fiber 402 (represented by cross-hatching in the figures) lies against atomizer 307. '745 Publication (Ex. 1005), ¶¶0009, 0031. In this configuration, fiber 402 is located inside the atomizer assembly housing.

45. Accordingly, Figures 5A, 5B, and 12 of the '819 Application describe precisely what is recited in independent claim 1 of the '550 Patent, namely an electronic cigarette comprising a liquid supply in a tubular atomizer assembly housing.

46. Collins argues that "[n]othing in the specification…suggests that the bottle assembly is optional or could be replaced with some alternative structure for storing liquid." Collins (Ex. 1003), ¶93. However, removal or replacement of the

bottle assembly is not required to arrive at the '550 Patent claims—the figures show the liquid supply inside the atomizer assembly housing.

The term "this invention" in the '819 Application is used to describe an example embodiment, not a requirement of the disclosed electronic cigarettes

47. Petitioner and Collins point to several instances of the term "this invention" in the '819 Application, and argue that these instances support their argument that the '819 Application necessarily requires a third assembly. For example, Petitioner and Collins cite the "Description of the Drawings" section of the '819 Application, in which each figure description refers to a specific component of "this invention." Petition (Paper 1), p. 56; Collins (Ex. 1003), ¶91; both citing '745 Publication (Ex. 1005), ¶¶0011-0024. However, the majority of these figure descriptions do not relate to a bottle assembly or to a complete device containing such an assembly (see, e.g., Ex. 1005, ¶¶0012-0014, 0018-0023). Further, the descriptions of Figures 5A and 5B, which show a complete vaporizing device that includes a cigarette bottle assembly, refer to those figures as "one internal structure of this invention" and "another internal structure of this invention," respectively. '745 Publication (Ex. 1005), ¶¶0016-0017. One of ordinary skill in the art would interpret this language to mean that the devices in these figures are examples of the disclosed devices, not absolute requirements.

48. Petitioner and Collins also cite to the "Contents of Invention" section of the '819 Application. Petition (Paper 1), pp. 54-56; Collins (Ex. 1003), ¶90;

both citing '745 Publication (Ex. 1005), ¶¶0008-0009. The "Contents of Invention" section describes the purpose of the disclosed devices, and how that purpose is fulfilled. Specifically, this section recites that the purpose of the disclosed invention is "to provide an emulation aerosol sucker that substitutes for cigarettes and helps the smokers to quit smoking." '745 Publication (Ex. 1005), ¶0006. Later, this section lists a series of "benefits and active effects" of the disclosed devices, specifically, "[f]or this invention, smoking doesn't bring any cigarette tar, considerably reducing the carcinogenic risks. At the same time, the smokers can still enjoy the feel and excitement of smoking, and there is no fire hazard since there is no need for igniting." '745 Publication (Ex. 1005), ¶0010. One of ordinary skill in the art would recognize that the cigarette bottle assembly is not necessary to the enumerated purposes and benefits. The "Contents of Invention" section goes on to provide an extensive laundry list of features that can be used to fulfill that purpose, including a cigarette bottle assembly. '745 Publication (Ex. 1005), ¶¶0008-0009. One of ordinary skill in the art would recognize that the written description of the '819 Application is not limited by all of the specific features laid out in this laundry list and that it is not necessary to include every disclosed feature to fulfill the stated purpose, including the cigarette bottle assembly.

The '819 and '521 Applications describe all limitations of the '550 Patent claims

49. I have reviewed the '819 and '521 Applications and it is my opinion that one of ordinary skill in the art would understand both of these applications to describe every limitation of the challenged '550 Patent claims, as illustrated in the claim chart set forth in Exhibit 2005.

Conclusion

50. I conclude that the '819 Application provides written description support for claims 1-12 of the '550 Patent, and that Petitioner has not shown a reasonable likelihood that any one of those claims is unpatentable over the '745 Publication.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: December 13, 2016
in Escondido, CA

Richard Meyst

Richard Meyst

Exhibit A

CV for Richard P. Meyst

Selected Expertise

- Medical Product Design / Development
- FDA-GMP Practices
- Market / Patent Research
- Rapid Prototyping
- Tooling / Process Development
- Manufacturing / Industrial Engineering
- Project Planning / Management
- Risk Analysis / Risk Management
- Failure Analysis
- Verification, Validation & Qualification
- Regenerative Medicine Devices
- Blood Filters, IV Filters
- Laparoscopic Surgical Instruments
- Umbilical Cord Blood Collection
- Cell Therapy, Stem cells & bioreactors
- Catheter Based Diagnostics
- Therapeutic Catheters, angioplasty
- Drug Delivery/ Infusion Devices
- High Volume Sterile Disposables
- Medical Device Regulatory Submissions
- Grant Writing
- Expert Witness

Biography

Mr. Meyst is an accomplished engineer/program manager/entrepreneur and has been facilitating the advanced design and development of a wide range of successful medical technology products for the health care industry over the last 40+ years. He has extensive knowledge in product design and development, product prototyping, production startup, manufacturing engineering, risk analysis, strategic planning, grant preparation and market research. He has also provided expert witness assistance in IP cases, product failure analysis, and other medical products cases. He has held various engineering, development, operations and management positions at CR Bard, Fenwal Division of Baxter, IMED and other healthcare and consumer product companies. For the last 25+ years he has been an owner of Fallbrook Engineering. Since 2003 he has been the President and CEO. Selected product experience includes implantable vascular prosthesis, DNA amplifiers, vital signs monitoring, drug infusion pumps and systems, medical lasers, surgical instruments, catheters of all kinds, microprocessor based diagnostic and therapeutic instruments, blood cell collection and processing, filtration devices for blood and IV solutions, as well as stem-cell harvesting and cell expansion systems.

Mr. Meyst was recently a Principal Investigator on an NIH SBIR grant from the National Heart, Lung and Blood Institute developing a device for the improved collection of Umbilical Cord Blood Stem Cells. He served on the Board of Directors for the Society of Plastics Engineers/Medical Plastics Division and is a long time member. He is a member of the American Association of Blood Banks, the Association for the Advancement of Medical Instrumentation and the American Filtration Society. He is also a member of the Medical Device Steering Committee of BIOCOM. Mr. Meyst has recently been a juror in the UBM/Cannon Medical Design Excellence Awards competition. His Bachelors and Masters degrees in Mechanical Engineering are from the University of Wisconsin, Madison. He has been awarded sixteen US Patents, has over four applications pending and has been an invited speaker, presenting talks at numerous scientific and medical industry meetings.

Employment History

From: 1989 **Fallbrook Engineering, Inc.**
To: Present Escondido, CA

Position: ***2003-Present: President/CEO***
Fallbrook provides consulting engineering services to client companies in the medical, pharmaceutical, biotech, electronic and consumer product industries. Services include project management, product conception, design and development, product prototyping, design and process validation, manufacturing engineering, production startup, cost reduction, as well as regulatory affairs compliance and submissions. He was also a Principal Investigator on a Phase II NIH SBIR Grant for the development of an improved method for the collection of umbilical cord blood, a source rich in stem cells.

1989-2003: Vice President
Provided consulting engineering services to client companies in the medical, pharmaceutical, cosmetic, electronic and consumer product industries.

From: 1988 **Diatek Corp.**
To: 1989 San Diego, CA

Position: ***Manager, Manufacturing Engineering***
Designed/developed disposable for "next generation" tympanic electronic hospital thermometer. Designed and implemented high speed automated production equipment to produce 1 MM+ units per day. Supported existing vital signs and operating room product lines. Managed facility and plant maintenance departments.

From: 1983 **Imed Corp.**
To: 1988 San Diego, CA

Position: ***Manager, Pilot Engineering***
Ran pilot production facility for new product builds of complex medical electromechanical/electronics and sterile disposables. Managed "Specials" program to offer custom I.V. sets and I.V. pumps per hospital order. Managed team of technicians/engineers to move new products from R&D into Manufacturing.

Technical Product Manager
Managed I.V. disposables product line projects that resulted in $4 MM annual savings. Developed organized plan, gained corporate support and supervised implementation. Achieved project objectives through design standardization, process simplification, quality/performance enhancements, plus multi-national manufacturing operations.

Manager, Disposable Design
Managed/directed design & implementation of 6 new I.V. disposable product codes, an enteral product line and numerous new components. Supported research of 3rd generation volumetric pump disposable. Supervised department's growth in handling design/drafting, engineering and technician support.

From: 1979 **Oak Industries**
To: 1983 San Diego, CA

Position: ***Manager of Telecommunications***
Consulted to headquarters and domestic operating companies. Managed $500K annual acquisition and installation of telecom equipment/services. Utilized cost control programs, network optimization and the use of value-added services to save $350K annually.

Manager, Training & System Development
Planned and directed implementation of facilities projects for nationwide Pay TV network offices/warehouses in Phoenix, Chicago and Dallas. Designed and supervised training programs for installers, service technicians, phone sales and billing agents. Improved overall efficiency by 40% and saved 20% labor cost. Planned/directed the buying and installation of telecom equipment/services serving 600+ users handling 20,000 calls per day.

From: 1974 **Baxter Travenol Labs, Fenwal Division**
To: 1979 Round Lake, IL

Position: ***Program Manager***
Supervised and directed experts in design/development of collection, fractionation, storage and administration of human blood component products. Product scope: sterile medical disposables and electronic, electro-mechanical biomedical hardware. Specific products: Membrane Plasmapheresis, Autologous Blood Collection and General Blood Collection & Administration Sets.

Section Manager
Directed 6 engineers, physiologists and technicians in R&D for entire blood filtration product line. Simplified several blood set codes with 30% increase in manufacturing yield. Pioneered blood set materials evaluation for conversion from ETO to Gamma Sterilization. Designed nonwoven composite filter cartridge for Cadiotomy Bypass Filter. First of code production achievements: Polyester Mesh Blood Administration Sets, Pediatric Microfilter and a Filtration Leukapheresis Disposable Circuit.

Senior Biomedical Engineer
Designed/tested and produced a Microaggregate Transfusion Filter product line for worldwide distribution. (Product performance remained tops through 20+ years of product life. Product is now discontinued.) Served on AAMI Microfilter Standards Committee. Redesigned Platelet Administration Set to improve yield 20%. Managed design of an Autologous Blood Collection Set. Developed filter for collecting cryoprecipitate to produce Factor VIII.

Senior Development Engineer
Reduced Blood Sets' field complaints by 50% through product redesign and manufacturing process modifications. Redesigned existing microfilter to double volume capacity with no cost increase. Introduced ultrasonic assembly techniques for several products to reduce costs and improve reliability.

From: 1972 **USCI, Division of C.R. Bard, Inc.**
To: 1974 Glens Falls, NY

Position: ***Product Engineer, Prosthetic Development***
Supported Vascular Graft and Cardiovascular Catheter product lines. Instituted program to quantify and control variables affecting product quality. Designed/implemented/evaluated specialty test equipment and testing procedures. Developed/wrote product specifications.

Expert Witness, Litigation Experience

Date:	2016	**Client: Gallagher Krich, APC**
	Case:	Cyth Systems v. CareFusion
	Project:	Contract dispute
Date:	2016	**Client: Davis, Grass, Goldstein & Finlay**
	Case:	Beatriz Picon v. San Antonio Regional Hospital
	Project:	Failure analysis
Date:	2016	**Client: Cooley LLP**
	Case:	Medline Industries, Inc. v. C.R. Bard, Inc.
	Project:	Patent dispute
Date:	2016	**Client: Hodgson Russ LLP**
	Case:	Curlin Medical, Inc. v. ACTA Medical, Inc.
	Project:	Patent infringement
Date:	2016	**Client: PJ West and Associates, Inc.**
	Case:	Undisclosed
	Project:	Medical product failure
Date:	2016	**Client: Girardi and Keese**
	Case:	Deirdree Lagewaard v. Medtronic Minimed, Inc.
	Project:	Medical product failure analysis
Date:	2015	**Client: Perkins Coie LLP**
	Case:	Fontem Ventures B.V. ET AL v. Njoy Inc. ET AL
	Project:	Electronic Cigarette IP case: Infringement, Validity and IPRs
Date:	2014	**Client: Novak Druce Connolly Bove & Quigg LLP**
	Case:	Larry G. Junker, Plaintiff v. Medical Components, Inc. and Martech Medical Products, Inc., Defendants
	Project:	Catheter design patent

Date:	2014	**Client: Lipeles Law Group**
	Case:	Robinson v. Rheingold
	Project:	Analysis of failed knee brace
Date:	2014	**Client: Law Offices of George B. Piggott**
	Case:	Armand Maaskamp v. Theodore Wortrich
	Project:	Technology Ownership and Contracts Dispute
Date:	2014	**Client: Knobbe Martens Olson & Bear LLP**
	Case:	Masimo Corporation & Masimo International Sarl v. Shenzhen Mindray Bio-Medical Electronics., Ltd.
	Project:	I.P. – Patent Infringement and Validity
Date:	2014	**Client: Johnson Moore**
	Case:	Rosenwein v. UCLA Hospital, Bard Access Systems, Inc.
	Project:	Patient Injury, Root Cause Investigation of Medical Device
Date:	2014	**Client: Orrick, Herrington & Sutcliffe LLP**
	Case:	Flextronics v. ICU Medical
	Project:	Development Project Arbitration Matter
Date:	2014	**Client: Leavitt, Yamane & Soldner**
	Case:	Pre-case Evaluation
	Project:	Patient Injury, Root Cause Investigation of Medical Device
Date:	2012	**Client: Weiss & Moy PC**
	Case:	Pacific Bioscience Labs Inc. v. Nutra Luxe MD, LLC
	Project:	I.P. – Patent Infringement
Date:	2012	**Client: Thomas Whitelaw**
	Case:	Pabban Development, Inc. v. Kyphon Sarl and Medtronic, Inc.
	Project:	Contract Dispute
Date:	2012	**Client: Gwilliam Ivary Chiosso Cavalli & Brewer**
	Case:	Diane Ely v. Barrx Medical, Inc. et al
	Project:	Patient Injury, Root Cause Investigation of Medical Device

Patents

Patent Number	Date Issued	Title
8,522,839	2013	Adapters for use with an anesthetic vaporizer
8,033,306	2011	Adapters for use with an anesthetic vaporizer
7,784,504	2010	Adapters for use with an anesthetic vaporizer
6,669,092	2003	Display apparatus
6,440,110	2002	Apparatus and method for collecting blood from an umbilical cord
6,190,368	2001	Apparatus and method for collecting blood from an umbilical cord
5,993,429	2001	Apparatus and method for collecting blood from an umbilical cord
5,919,176	2001	Apparatus and method for collecting blood from an umbilical cord
RE34,599	1994	Disposable probe cover assembly for medical thermometer
D336,862	1993	Probe cover holder for medical thermometer
5,056,682	1991	Container for fan-folded sheets
4,911,559	1990	Disposable probe cover assembly for medical thermometer.
4,736,736	1988	Cervical traction assembly having head cradle w/ occipital shelf
4,283,289	1981	Blood filter for leukocytes
4,170,056	1979	Blood filter
4,157,967	1979	Blood filter

Education

Year	College/University	Degree
1972	University of Wisconsin, Madison, WI	MS, Mechanical Engineering
1971	University of Wisconsin, Madison, WI	BS, Mechanical Engineering

Publications / Presentations

1. "Effective Strategic Alliances", Tech Coast Life Science Innovation Conference, September 28, 1999
2. "Effective Strategic Alliance Tactics", Tech Coast Life Science Innovation Conference, September 28, 2000, Irvine, CA.
3. "Strategies for Optimal Outsourcing Alliances", MD&M West 2001, January 9, 2001, Anaheim, CA.
4. "Winning Strategies for Commercialization", Tech Coast Life Science Innovation Conference, November 13, 2001, Irvine, CA.
5. "Seeing Green: Finding Money for Product Development" A Presentation for the 2002 Medical Design & Manufacturing Conference, Jan., 2002, Anaheim, CA.
6. "Running the Hurdles with NIH SBIR's" A Presentation for the 4th Annual NIH SBIR/STTR Conference, June 21, 2002, Bethesda, MD
7. "Running the Hurdles with NIH SBIR's", A Presentation for the 5th Annual Winter Conference, Association of University Research Parks, January 17, 2003, Newport Beach, CA
8. "NIH Grant $ for Your Med Device/Biotechnology Project", Medcon, Conference for the Design and Manufacturing of Medical and Biotech Devices, April 28, 2004, Del Mar, CA
9. "NIH Grant $ for your Nano-Biotechnology Project", A Presentation for the nanoSIG™ Forum, Commercial Applications in Nano-Bio Technology, February 26, 2004, San Diego, CA
10. "It's a risky world out there. Using Risk Management as a tool to ensure success in medical product design and development." A Presentation to the 2005 AOAC Two-Day cGMP Conference on Pharmaceuticals and Medical Devices, March 10 & 11, 2005, FDA Offices, Irvine, CA
11. "It's a risky world out there. Using Risk Management as a tool to ensure success in medical product design and development." A presentation for Medcon Expo April 28, 2005, Del Mar Fairgrounds, San Diego, CA
12. "Development of a new medical device for the efficient, safe and easy collection of umbilical cord blood." A presentation at the BIOCOM Medical Device Quarterly Event, August 11, 2005, San Diego, CA
13. "Risk Assessment: It's a Risky World out There" A presentation to the San Diego Regulatory Affairs Network, March 16, 2006, San Diego, CA

14. “Device & Diagnostic Development: Concept to Bedside” Panel member at the BIOCOM Medical Device Quarterly Event, October 22, 2008, San Diego, CA
15. “Risk Assessment: It’s a Risky World out There” A presentation to a Masters Class at San Diego State University, April 2011, San Diego, CA
16. “Risk Assessment: It’s a Risky World out There” A presentation to a Masters Class at the University of California, San Diego, August 2011, San Diego, CA
17. “Bioresorbable Polymers with Medical Devices – A (Still) Emerging Field” A presentation to the Medical Device and Design West Conference, February 13, 2012, Anaheim, CA
18. “Cellect 250™, The Safest, Fastest and Most Effective Umbilical Cord Blood Collection System” A presentation to National Heart, Lung, and Blood Institute Innovation Conference, June 11, 2013, San Diego, CA
19. "Secrets to a Successful Startup" a panel member at 30th anniversary MD&M West Conferences, February 11, 2015 in Anaheim, CA

Professional Associations and Additional Activities

- Sr. Member, Society of Plastics Engineers (SPE), Medical Plastic Division
- Member, AAMI, Association for the Advancement of Medical Instrumentation
- Member, AABB, American Association of Blood Banks
- Member, AACC, American Association for Clinical Chemistry
- Member, American Filtration and Separations Society
- Member, BIOCOM, San Diego
- Member, The Designers Accord
- Member, SDRAN, San Diego Regulatory Affairs Network

- Served as a juror in the UBM/Cannon Medical Design Excellence Awards competition
- Served as a judge in a San Diego CONNECT Capital Competition for start-ups
- Advisor to Valley Center High School Computer Aided Design (CAD) program