Albert Juergens, III

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Patent Consultant and Expert Witness

EMPLOYMENT HISTORY:

• March 2010 – Present; OST Corporation – Principal

Engineering and patent consultant – expert witness specializing in: medical product design and development, patent prosecution, patent infringement, infringing product tear-down & evaluation, technical review, claim construction, and patent portfolio evaluation and management.

- October 2017 October 2018; American Optics Chief Technology Officer Responsible for the engineering and quality functions for an endoscopic device (rigid and flexible endoscopes) optical and mechanical component manufacturer. Charged with bringing new metrology and manufacturing techniques to enable working to closer tolerances with lowered manufacturing costs as well as assuring compliance with IEC13485:2016 standards.
- October 2008 February 2010; MicroGroup Chief Technology Officer Responsible for the specification and implementation of manufacturing technology and production processes for a \$48M medical device component manufacturer. 8 direct reports in two locations. Selected and introduced CAM software for CNC machine programming. Improved needle grinding capability. Improved cleaning processes and equipment.
- November 2004 October 2008; GyrusACMI (Olympus) Vice President, R&D Responsible for the development of visualization and disposables products in a \$400M company. 40+ direct reports including project managers, engineers, technicians, model makers, documentation specialists in three locations. \$8MM+ budget. Released over 15 new products and product upgrades in a two-year time frame with a focus on design for ease of manufacturing and containment of cost of goods. Part of leadership team prior to and during the time ACMI was acquired by Gyrus PLC.
- July 1981 November 2004; Brattas Corporation Principal Engineering consultant specializing in multi-discipline (mechanical, electronic, optical, software) product development. See details on project experience below.
- June 1979 June 1981; Pratt & Whitney Aircraft Optical test engineer Responsible for the design, installation, and operation of optical test instrumentation for the evaluation of jet engine performance.

SUMMARY:

- 35+ years of experience in the development and market introduction of engineering intensive (hardware, software, mechanical, optical) products including multiple class II medical devices.
- Led multi-site R&D organizations of up to 40+ people & \$8MM+ budgets.

- Brought diverse products to market including urological wires, stents, and baskets; video cameras; flexible, rigid, and semi-rigid endoscopes (conventional and digital); ESU generators and electrodes; surgical and aesthetic lasers.
 - MR-6A autoclavable semi-rigid ureterscope
 - DURD first flexible digital ureteroscope
 - o Invisio megapixel snap-on CMOS camera head
 - o Titan autoclavable mega-pixel snap-on CMOS camera head
 - UroPass urological access sheath
 - Sure-Catch no-tip nitinol kidney stone basket
 - o OM5 urodynamics system
 - o CyberWand ultrasonic lithotripsy system
 - o DUR-HL20 holmium laser
 - o Pelleve S5 upgraded 120W electrosurgical generator
 - o Cheveux 500W diode laser
 - o Medley multi-modal laser (erbium, diode, NdYAG, IPL)
 - o Ruby ruby laser
 - o Pelleve & Pellefirm wrinkle reduction systems for face and body
- Experienced in:
 - Building and leading cross-functional development teams across multiple sites including foreign collaborations
 - o Working with foreign (Asian, European, Israeli) suppliers and co-developers,
 - Patent prosecution & defense,
 - o M&A activities on both buying and selling side of transaction.
 - Medical device standards & requirements: IEC-60601 (Medical Electrical Equipment), 21 CFR 820 (Quality Systems and Design Controls), IEC-62304 (Medical Device Software), IEC-62366 (Medical Device Usability), 510K's, risk management, ISO-10993 (Biocompatibility), MDD 93/42/EEC (EU regulations)

MEDICAL PRODUCT EXPERIENCE:

- Aesthetic and Surgical lasers
 - Worked with Chinese, British, and Danish laser suppliers to develop, evaluate, and enhance their cosmetic lasers. This included CO2, Erbium YAG, diode, and Ruby lasers used for the purposes of skin resurfacing (fractional ablation) and hair removal. (Ellman International; New York 2010 to 2015)
 - Responsible for the evaluation of Holmium and green light lasers used for the purpose of kidney stone management and prostrate ablation (TURP) respectively. (Gyrus ACMI – 2004 to 2006)

- Artificial heart pump controller
 - Artificial heart pump controller all aspects of pneumatic and electronic hardware, firmware, and software design and implementation for a proof of concept prototype. Also, power supply and battery management systems. (Medical Equipment Manufacturer; Massachusetts – 1998)
- Audio systems for use by surgeons in the operating room and patients on CPAP
 - Acoustic microphone Design and bring to manufacture a dynamic throat microphone for end-stage patients on assisted breathing equipment (BiPAP or CPAP) meeting strict cost requirements. Includes design of voice coils, machined metal and plastic parts as needed to produce required magnetic fields, and molded silicone parts (Medical Equipment Manufacturer; Massachusetts 2016 & 2017)
 - Audio amplifier Design and build a pocket-sized battery powered amplifier for acoustic microphone (see above). Includes DSP audio processing software and battery charging hardware. (Medical Equipment Manufacturer; Massachusetts 2018)
 - Surgical audio system Bluetooth based battery powered operating room audio communications system for use by surgeons in the operating room. Included DSP board design, oversight of international programming team (India), design of power supply and charger and input into design of injection molded plastic case. (Medical Equipment Manufacturer; California 2001)
- Blood purification processing equipment
 - Blood purification processing equipment design & build digitally controlled pneumatic systems for proof of concept testing of donor blood processing equipment, including mechanical design, pneumatic control hardware, software and firmware development, and customization of electronic hardware (Medical Equipment Design Company; New Hampshire – 2001)
- Digital flexible ureteroscope & single and 3-chip endoscopic cameras
 - Subject matter expert on internals of endoscopic distal tip camera design for the purpose of evaluating infringement. Included tear-down of suspected infringing device to gain access and document internals. (Law Firm; Connecticut 2019)
 - Endoscopic Video Camera Subject matter expert witness providing detailed technical review and assessment of three-chip camera design (schematics, firmware, and software) to support patent infringement assertions. (Law Firm; Connecticut 2014 to 2019)
 - Miniature video system Direct the technical development of a miniature OEM video camera to be integrated in medical and/or industrial devices. Includes integrated optics and software-controlled illumination. Develop control hardware and software (Startup; Massachusetts and California 2010)
 - Flexible digital ureteroscope Responsible for all aspects of the development of the industry's first flexible ureteroscope utilizing a custom distal CMOS sensor. Interfaced with chip layout and fabrication team, as well as hands-on detailed technical involvement in the in-house mechanical, optical, and electronic trouble shooting activities. (Gyrus ACMI 2005)

- Technical assessment Assess digital CMOS development capabilities and patent portfolio of potential acquisition, aid in the preparation of patent applications, evaluate and compare competing video product designs (Medical Equipment Manufacturer; Massachusetts & Israel 2004)
- 3-chip endoscopic video camera Developed custom shutter algorithm tailored for use in an endoscopic video camera. Also led redesign of plastic (Ultem) remote head enclosure for improving of sealing and ease of assembly. Managed pre-production phase and software development team. (Medical Equipment Manufacturer; California 1999 to 2000)
- Electrosurgical generators
 - Electro-surgical generator (ESU) Design 150W multi-processor generator (hardware, software, firmware) for Chinese surgical / aesthetic market. (Medical Device Manufacturer; Beijing, China 2016 & 2017)
 - Electro-surgical generator (ESU) and hand-piece Design new 50W multi-processor generator (hardware, software, firmware, & industrial design) and modify hardware and software of existing product to enhance performance, correct for malfunctions, and reduce EMI. (Ellman International; New York 2010 to 2015)
- Heads up display for use by surgeons in the operating room
 - Heads up display for use by surgeons in the operating room Design of high power (60W) infrared video transmitter including power supply and video amplifiers along with plastic/metal case design and cooling fan integration. (Medical Equipment Manufacturer; California 2001)
- Inter-uterine fluid management system
 - Inter-uterine fluid management system design and develop electronic hardware (digital & analog) and firmware. Tailor control algorithm to handle the unique hydraulic pressure profile presented by the design and use of this device. Assist with overall software system architecture and coding of low-level routines. Supervise the administration of US and FDA compliance testing and provide technical input to regulatory department for the purpose of preparing the 510K submissions. (Medical Equipment Manufacturer; California 1996 to 1997)
- Optical Systems
 - MR-6A autoclavable semi-rigid ureterscope Responsible for the release of an enhanced semi-rigid endoscope for urology applications. Scope included improved fused fiber bundle and optical design capable of withstanding autoclave sterilization. (Gyrus ACMI 2004 to 2006)
 - Technical evaluation Assess the equipment and methods of an endoscope repair facility (Canada) and endoscopic (miniature) lens manufacturing factory (Bulgaria) for technical competence and conformity to applicable standards. (Venture Capital Fund; Massachusetts 2017)
 - Subject matter expert on internals of rigid optical endoscope design and repair procedures for the purpose of evaluating infringement. (Law Firm; Connecticut 2019)

PATENTS:

- US Patent #10,492,849 Surgical instruments and systems with multimodes of treatment and electrosurgical operation (assigned to Cynosure, Inc.)
- US Patent #10,143,831 Electrosurgical systems and methods (assigned to Cynosure, Inc.)
- US Patent # 8,233,075 User-aided auto-focus (assigned to Gyrus Group PLC)
- US Patent # 7,313,246 Information system using eyewear for communication (assigned to Optimize, Inc. (assigned to Stryker Corporation))
- US Patent # 6,729,726 Eyewear for hands-free communication (assigned to Stryker Corporation)
- US Patent # 6,032,843 Longitudinal transport of laterally curved resilient strip
- US Patent # 5,497,060 Positioning stage
- US Patent Application # 20140276801 Electrosurgical Systems and Methods
- US Patent Application # 20140276768 Electrosurgical Systems
- US Patent Application # 20140276659 Surgical Instruments and Systems with Multimodes of Treatments and Electrosurgical Operation (assigned to Ellman International)
- US Patent Application # 20130006239 Electrosurgical Systems and Methods (assigned to Ellman International)
- US Patent Application #20090046196 User-aided autofocus (assigned to Gyrus Group PLC)
- US Patent Application # 20030068057 Information system using eyewear for communication (assigned to Optimize, Inc. (Stryker Corporation))
- US Patent Application # 20030067585 Eyewear for two-way communication (assigned to Optimize, Inc. (Stryker Corporation))

EDUCATION:

• B.S. Physics, Fairfield University, Fairfield, CT 1979.

PERSONAL:

Fluent in German, Traveled extensively throughout US, Europe and Asia, Past Member New Fairfield (CT) Board of Education, Hobbies in metal fabrication (welding and machining) and woodworking

TESTIFYING EXPERT WITNESS MATTERS:

3:14-cv-00876 Karl Storz Endoscopy v. Stryker Corporation et al.

2:12-cv-02716-KOB Karl Storz Endoscopy v. Integrated Medical Systems International

Inter Partes Review - Case IPR2020-00152 - Intuitive Surgical, Inc. v. Rex Medical, L.P.

19-cv-00005-MN – <u>Rex Medical, L.P.</u> v. Intuitive Surgical, Inc.