BORIS LESCHINSKY

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PATENT AND MEDTECH LITIGATION EXPERT WITNESS

Senior medical device expert with broad expertise in cardiovascular and endovascular fields with a focus on percutaneous catheters, heart assist devices, perfusion and blood pumps, percutaneous aneurysm treatments, and vascular closure products.

Inventor with over 50 US and many more international Patents in various medical technologies and other fields.

Experienced Expert Witness – assisted in several major patent and product litigations since 2017

PROFESSIONAL EXPERIENCE

CORINNOVA INC. (since 2013) – **Vice President, Product Development**
Medical device start-up, remote position

- Leading a small engineering team and coordinating several external vendors in developing a novel external compression cardiac assist device:
  - Development of thin-film polyurethane multi-segment inflatable subassemblies
  - Development of NiTinol wire frame and hub structures
  - Development of miniaturized pressure monitoring of the passive and active inflatable chambers
  - Development of insertion and delivery methods and devices
  - Development of a pneumatic driver and controller for operating the device
  - Development of bench test methods and devices for fatigue and other tests
- Primary Investigator on animal studies and NIH grant applications

FRESH CONCEPT DESIGN CORP. (since 1995) – **President**
Sole principal – R&D and patent consulting services. Involved with a broad range of medical devices, including nebulizers, subcutaneous ports, dialysis machines, perfusion and infusion pumps, ultrasound and other imaging devices, patient monitors, etc. Prepared and filed over 350 patent applications

LifeCuff Technologies Inc. (since 2009) – **Founder**
Part-time position with a medical device company developing automated devices for remote ischemic conditioning based on 10 issued US patents.

CERUS ENDOVASCULAR Inc. (2009 to 2013) – **CTO**
Leading a start-up team in developing proprietary non-invasive devices for treating brain aneurysms

DATASCOPE Corp., Montvale, NJ (1990 to 2009)
Diversified medical device company with $400 million total sales volume and major product lines in intra-aortic balloon pumping, patient monitoring, vascular sealing, and vascular grafts

Vice President, Technology (Aug 2005 to Feb 2009)
Responsible for directing R&D activities of all four divisions of the company with a total budget of $30+ million, regular market introductions of new products, identifying organic growth opportunities as well as technical and IP assessment for new business development and technology acquisitions

- Invented a key concept for a new revolutionary catheter-based heart assist device combining a low-profile insertion with full-flow assist capability – Percutaneous Heart Pump (PHP)
- Led internal and external technical teams with a combined yearly budget of $2 million in developing this concept through feasibility and achieving major performance goals
- Acquired by Abbott for **$450 million** in 2016 after obtaining CE Mark

- Completed detailed technical and patent due diligence assessments on 100+ acquisition targets

Scientific Director (Oct 1998 to Aug 2005)
Responsible for advanced development of new generations of company products, primarily in the fields of counterpulsation, vascular closure and endovascular aneurysm treatment devices

Early Positions: **Engineer** (1990 to 1994), **Sr. Research Engineer** (1994 to 1995), **Principal Engineer** and **Sr. Principal Engineer** (1995 to 1998)

SCIENTIFIC INSTITUTE FOR TRANSPLANTOLOGY AND ARTIFICIAL ORGANS, Moscow, Russia (1987 to 1990)
Lead Engineer – artificial heart laboratory (1988 to 1990)
- Controlled performance of the first Russian artificial heart in limited clinical use on 10 patients
- Implanted and evaluated outputs of several artificial heart prototypes in large animals
- Invented and patented 5 new concepts for centrifugal blood pumps

Engineer (1987 to 1988)

EDUCATION

Masters in Mechanical Engineering – Moscow State Technical University, Russia, 1987
Advanced Ph.D. courses in biomedical sciences – Moscow, Russia, 1990

OTHER QUALIFICATIONS

Registered Patent Agent with US Patent and Trademark Office

Inventions
- Named inventor in 55 US and 70+ international patent filings (published patents list here)
- Sole inventor or co-inventor in 40% of all patent filings by Datascope between 1990 and 2009
- 2009 "Inventor of the Year" nominee for a lifetime of innovation achievements

Other
- Authored a number of peer-reviewed articles, abstracts and oral presentations at scientific conferences
- Invited speaker at 2008 Medical Device and Manufacturing Conference
- Invited moderator for 2007 ASAIO conference
- Listed Reviewer for ASAIO Journal
- Adviser for a Ph.D. thesis at PennState University

PUBLICATIONS

- G. V. Letsou, **B. Leschinsky**, W. Altman, C. Bolch, E. Hord, J. C. Criscione. 14-day End-Organ Safety and Hemocompatibility with the CorInnova Direct Cardiac Compression Device in an Ovine Chronic Heart Failure Model. Poster at THT 2023.
- G. V. Letsou, **B. Leschinsky**, W. Altman, C. Bolch, E. Hord, J. C. Criscione. A New Implantable Direct Cardiac Compression Device Improves Cardiac Performance in a Chronic Ovine Heart Failure Model. Poster at ISHLT 2023.
- G. V. Letsou, **B. Leschinsky**, W. Altman, C. Bolch, E. Hord, J. C. Criscione. Implantable Direct Cardiac Compression Devices Do Not Cause Cardiac Injury or Induce Thrombus Formation. Poster at ISHLT 2023.
- Letsou GV, Bolch CM, Hord EC, Altman WC, Youngblood BL, **Leschinsky B**, Criscione JC. Mechanical Cardiac Support With an Implantable Direct Cardiac Compression Device: Proof of Concept. Ann Thorac Surg (in press) 2022.
- Letsou GV, Bolch CM, Hord EC, Altman WC, **Leschinsky B**, Criscione JC. The CorInnova Implantable Cardiac Assist System for Direct Cardiac Compression. Rev. Cardiovasc. Med. 23(6), 211, 2022.
- Letsou GV, **Leschinsky B**, Hord E, Bolch C, Criscione J. Effective Diastolic Mechanical Support Using a New Implantable Cardiac Compression Device. The Journal of Heart and Lung Transplantation. 40: S103–S104, 2021.
- Letsou GV, **Leschinsky B**, Hord E, Bolch C, Criscione J. Mechanical cardiac support using a new implantable cardiac compression device. 101st AATS annual meeting, Oral presentation, 2021.

- Letsou GV, Bolch C, Hord E, **Leschinsky B**, Criscione J. Extracardiac Mechanical Support Device Placement by a Minimally Invasive Approach is Safe and Effective. The Journal of Heart and Lung Transplantation. 39: S189–S190, 2020
- Hord EC, Bolch CM, Tuzun E, Cohn WE, **Leschinsky B**, Criscione JC. Evaluation of the CorInnova Heart Assist Device in an Acute Heart Failure Model. J Cardiovasc Transl Res 12(2):155-163, 2019.
- Garratt KN, **Leschinsky B**. Remote Ischemic Conditioning: The Commercial Market: LifeCuff Perspective. J Cardiovasc Pharmacol Ther. Sep;22(5):408-413, 2017.
- Ohley WJ, Antonelli L, **Leschinsky B**. Influence of catheter and arterial diameter on flow distal to an intra-aortic balloon insertion site: a theoretic examination and in vitro assessment. ASAIO J. Nov-Dec;44(6):786-93, 1998.
- **Leschinsky B**, Itkin GP, Zimin NK. Centrifugal blood pumps--a brief analysis: development of new designs. Perfusion.6(2):115-21, 1991.

SERVICE

Reviewer for National Institutes of Health grant applications

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EXPERT WITNESS

- 2019-2021 – and currently ongoing *Abiomed, Inc. v. Maquet Cardiovascular, LLC*, No. 1:16-cv-10914 (D. Mass.) (provided expert report; testified at deposition)
- 2021 *Atrium Medical Corporation v. Bard Peripheral Vascular, Inc.*, IPR2021-01197 (PTAB) (provided expert declaration)
- 2021*Atrium Medical Corporation v. Bard Peripheral Vascular, Inc.*, IPR2021-01199 (PTAB) (provided expert declaration)
- 2021*Atrium Medical Corporation v. Bard Peripheral Vascular, Inc.*, IPR2021-01200 (PTAB) (provided expert declaration)
- 2022 *Abiomed, Inc. v. WhiteSwell Medical Ltd*, PGR2021-00107 (provided expert report; testified at deposition)
- 2023 *Robert Lerner v. Cascade Designs, Inc.,* Case 01-21-0004-7081 (provided expert report; testified at deposition)
- 2024 *Hsin Lin vs Solta Medical, Inc.*, Case 4:21-CV-05062-PJH (provided expert report; testified at deposition)
- 2024 *Insulet Corporation v. EOFlow Co.*, Case 1:23-CV-11780-FDS (provided expert report; testified at deposition and trial)