Terry Earl Brady

Since relocating to the Caribbean and moving beyond traditional corporate roles, Terry Earl Brady has guided formation of Kepley BioSystems, Inc. and AT Research Partners, participated in original research and publications, multiple National Science Foundation (NSF) Small Business Innovation Research (SBIR) development grants, and pursued an "invent first" strategy to protect several inventions through the successful *pro se* prosecution and issuance of multiple patents. His interests include infectious disease diagnostics and novel contraceptive (family planning) methods using functionalized fullerenes, as well as oceanic species restoration and sustainability, obesity, unassisted robotic surgery, organ preservation and tissue transplantation.

Under the COVID-19 Prioritized Examination Pilot Program, AT Research Partners submitted and was awarded two United States Patent and Trademark Office (USPTO) patents. Both inventions were filed *pro se* and qualified for issuance within one year. As *pro se* inventors, US Patents Nos. 10,934,168 and 11,219,255 are directed at bioactive biocidal fullerene coatings and safe, sterile delivery of inhalation and exhalation breath, respectively. In late 2021, a third *pro se* invention was filed under accelerated review for a biocidal fullerene contraceptive, which was awarded in February 2022 as Brady, et. al., No. 11,298,375. These innovations were then applied to organ and tissue preservation with a fourth submission and *pro se* award, No. 11,452, 288, issued on September 27, 2022.

AT Research Partners, initially constrained by pandemic lockdowns, recognized the paradoxical challenge of unprotected bench research too often lost in unmanaged notebooks and years of forced financial collaboration for intellectual property and novel development. By leveraging years of knowhow and academic research, the "invent first" model has been focused on IP protection prior to perfecting the art. By ensuring unfettered commercial protection during development, their patent work has secured a pathway to billion-dollar markets with complementary opportunities for established sector leaders who can benefit from acquisition of the IP – while continuing to focus on further innovation at AT Research Partners. This work continues, along with exciting developments at Kepley BioSystems with respect to the global risks of antimicrobial resistance and sepsis mortality.

During much of 2021, Brady and collaborators completed an NSF Phase I SBIR grant to adapt the cellular blood component (Limulus amoebocyte lysate; LAL) of aquaculture *Limulus polyphemus* (Atlantic horseshoe crabs) for rapid detection and typing of gram-negative bacteria and fungal pathogens for sepsis screening and antibiotic susceptibility testing to mitigate antibiotic microbial resistance (AMR). The $1 million NSF Phase II grant was awarded in December 2022.

Brady's last operating position was President and CEO of Array Medical, Inc., Somerville, New Jersey. Formed in 1996, Array Medical was divested to Helena Laboratories in 2000 and included a product line consisting of: Actalyke® Activated Clotting Time System; Ichor® Self-contained Point-of-care Hematology Instrument; Nicky® Neonatal Heel Incision Device for blood sampling; and the Triplett® Bleeding Time Test technology. Selling into over 50 countries, the Array Medical target markets included point-of-care monitoring and management of thrombotic conditions such as stroke, heart attack and pulmonary embolism. Notably, the Array Medical complement of products remain in commercial use today with continued competitive performance.

Prior to forming Array Medical, Brady was President of International Technidyne Corporation (ITC) Commercial Group, Edison, New Jersey. ITC specialized in hemostasis monitoring for blood anticoagulation in bypass surgery and percutaneous transluminal coronary angioplasty (PTCA). In 1984, ITC was a single-product company with 20 employees and faltering sales nearing $1 million.

Brady was recruited into an equity position to turn the company around and divest. During his tenure, ITC ultimately delivered 36 quarters of double-digit growth averaging 35% per annum by 1991. ITC was renowned for clinically relevant products and exceptional promotion and advertising. Significant innovations included the development of the first FDA-cleared patient self-testing product for warfarin management (ProTime®) and the first acute care drug/diagnostic device integration of the RxDx® anticoagulation management system for coronary bypass surgery and angioplasty. In September 1991, ITC was acquired, in a pooling of interest merger by Thermo Electron Corporation (Fortune 300) for $35 million ($75 million in 2022 dollars and 35X earnings). Thermo Electron engaged Brady for two additional years, doubling revenue to $30 million by 1994 with 200 employees. ITC core products and technologies developed under Brady's leadership remained profitable and continue to serve as market leaders, commanding substantial premiums to date.

The ITC success was directly related to Brady's product development efforts prior to joining the firm at WT Associates, an R&D partnership co-founded by Brady. WT Associates licensed Surgicutt® (bleeding time test) and Tenderfoot®(neonatal heel incision) to ITC and enjoyed royalties from both products from 1985 to 1991, when the license was sold separately to Thermo Electron Corporation for $4 million (1,000X royalty cash flow), valued on market acceptance and growth in parallel to the merger with ITC.

Earlier in his career, Brady entered the discipline of diagnosing and managing thrombosis when he joined the sales force of Bio/Data Corporation, Horsham, Pennsylvania, in 1975. Bio/Data was the leading developer of hemostasis equipment and reagents. The renowned, late Bio/Data executive, James W. Eichelberger, personally mentored Brady while at Bio/Data. A commanding 6' 8" in height, Eichelberger funded his science education playing basketball with the Harlem Globetrotters. Before joining Bio/Data, Eichelberger led development of the world's first commercial coagulation reagents and controls. He was a vibrant teacher of coagulation and bench methods, publishing the first clinical laboratory technical manual for blood coagulation when labs used 'homemade' reagents, cited in *The New York Times* in 1964.

Brady's marketing and sales management expertise was honed in positions with Ortho Diagnostics (Johnson & Johnson), Union Carbide (Medical Products Division) and Baker Instruments. Before founding Array Medical and during a period of restricted employment and non-competition, Brady was a founding director in Gladstone Partners, a consulting firm specializing in identity and promotion. Brady's academic background was in the social sciences, excelling in a dual major of Sociology and Afro-American Studies at the University of South Florida (1971) in Tampa. He served four years with the United States Coast Guard and funded his university education as a tugboat captain while completing his Baccalaureate degree in three years.

From 2000 through 2014, Brady held an appointment as advisor to Luna nanoWorks and strategic advisor to Luna Innovations (NASDAQ; LUNA) located in Roanoke, Virginia. Additionally, Brady sat on the Luna advisory board/committee that included business and public sector leaders who previously served US presidential administrations. Brady advised Luna Innovations regarding investor strategy and healthcare opportunities. The Luna business model included top research centers with defense and wireless and fiber optics communications expertise that also generated and developed derivative technologies. These related technologies included medical diagnostic contrast agents for magnetic resonance imaging (MRI) using the novel "Buckyball" molecule as an endohedral metallofullerene ($Sc_3N@C_{80}$).

Today, Brady serves as chief inventor for Kepley BioSystems, Inc. and an *ad hoc* advisor to the Joint School of Nanoscience and Nanoengineering (JSNN) graduate program, a collaborative graduate program between the University of North Carolina at Greensboro (UNCG) and North Carolina A&T State University (NCA&T). Brady has applied the depth and breadth of his experience in product development, sales, marketing, and executive management from the start of his innovation journey when US patents were numbered in the 6 millions. His achievements encompass four "lead inventor" citations, including three patents that led to commercialization of Plateletworks® and MAXACT®, which have remained in active trade since the mid-1990s.

In 2021, he co-founded AT Research Partners with a business model dedicated to solving the riddle of building and protecting enterprise art. As patents approach the 12 millionth award, Brady is a rarified inventor whose work has spanned half of all US patent awards. When combined with numerous contributions to FDA applications and clearances, these innovations continue to reflect his enduring dedication to global solutions and intellectual property development.

Publications (Since 2015)

- Dellinger, A., Duncan, B., Robertson, L., Plotkin, J., **Brady, T.**, and Kepley, C. (2015). A synthetic crustacean bait to stem forage fish depletion. *Global Ecology and Conservation*, 7, pp.238-244. doi: 10.1016/j.gecco.2016.07.001.
- Krisfalusi-Gannon, J., Ali, W., Dellinger, K., Robertson, L., **Brady, T.**, Goddard, M., and Dellinger, A. (2018). The Role of Horseshoe Crabs in the Biomedical Industry and Recent Trends Impacting Species Sustainability. *Frontiers in Marine Science*, 5:185. doi: 10.3389/fmars.2018.00185.
- Williams, A., Cunningham, I., **Brady T.**, Abood, S., Tinker-Kulberg, R., Dellinger, K., Goddard, M., Robertson, L., Dellinger, A.* (2019). Use of a Canine Gastrointestinal Olfactory Stimulant in a Shelter Setting. *Journal of Animal Health and Behavioural Science*, 3(1).
- **Brady, T.**, Abood, S., Tinker-Kulberg, R., Dellinger, K., Robertson, L., and Dellinger A.* (2019). Initial Report: Canine Gastrointestinal Neurobiology Triggered by Olfaction. *Journal of Animal Health and Behavioural Science*, 3(1).
- Tinker-Kulberg, R., Dellinger, A., **Brady, T.**, Robertson, L., Goddard, M., Bowzer, J., Abood, S., Kepley, C., and Dellinger K. (2020). Effects of Diet on the Biochemical Properties of Amebocyte Lysates from Limulus Polyphemus in an Aquaculture Setting. *Frontiers in Marine Science*, 7:541604. doi: 10.3389/fmars.2020.541604.
- Tinker-Kulberg, R., Dellinger, A., Gentit, L., Fluech, B., Wilder, C., Spratling, I., Stasek, D., Kepley, C., Robertson, L., Goddard, M., **Brady, T.**, Tōland, L., and Dellinger K. (2020). Evaluation of Indoor and Outdoor Aquaculture Systems as Alternatives to Harvesting Hemolymph from Random Wild Capture of Horseshoe Crabs. *Frontiers in Marine Science*, 7:568628. doi: 10.3389/fmars.2020.568628.
- Tinker-Kulberg, R., Dellinger, K., **Brady, T.**, Robertson, L., Levy, J., Abood, S., LaDuca, F., Kepley, C., and Dellinger A.* (2020). Horseshoe Crab Aquaculture as a Sustainable Endotoxin Testing Source. *Frontiers in Marine Science*, 7:153. doi: 10.3389/fmars.2020.00153.

Patents

- Patent No. 10,934,168. *Bioactive/Antimicrobial, Non-Disposable Personal Protection Equipment that Safely Kills Viral, Bacterial, and Fungal Matter Upon Contact*. Brady, *et al.* Issued: Mar. 3, 2021.
- Patent No. 11,219,255. *Self-Contained, Mobile Breathing Apparatus or Appliance that Supplies Pathogen and Endotoxin Free, Rhythmically Breathable Air to the Wearer or Treated Space through Active, Continuous Bio-Deactivation and Destruction of Bacteria, Fungi, Viral and Allergenic/Antigenic Matter Safely when Using Benign, Household, Rechargeable Filtration Media.* Brady, *et al.* Issued: Jan. 11, 2022.
- Patent No. 11,298,375. *Halogenated Fullerene Functionalized as a Biocidal and Chemotactic Spermicide to Vaginally Harbor and Neutralize Spermatozoa for Use as a Safe and Effective Contraceptive.* Brady, *et al.* Issued: Apr. 12, 2022.
- Patent No. 11,452,288. *Innocuous Sterilant using Hemocyanin and Functionalized Fullerenes with Broad-Spectrum Intracellular and Interstitial Microbiocidal and Radical Scavenging Effects for Packaged Matter, Biologics and Organics including Liquids, Gases, Tissue, Organs, Cells, and Limbs with Copper Mediated Oxygenation for Viability and Preservation.* Brady, *et al.* Issued: Sept. 27, 2022.
- Patent No. 11,638,720. *Risk Mitigation of Infectious Disease Transmission from Incidental and Intimate Contact Using Atomic Scale Molecular Disruption and Biocidial Halo-fullerenes Delivery via Topical, Flushing and Enteral Mechanisms.* Brady, *et al.* Issued: May 2, 2023.
- Patent No. 11,653,984**.** *Unassisted Robotic Surgery Employing Paramagnetic Halo Metallofullerenes as Minimally Invasive, Precision Scalpels or Micronization Particles through Magnetic Field Manipulation and Targeted Exenteration Patterned by Programmed 3D Imaging Using Needle or Magnetic Energy Access and Microelectronic Semiconducting in Non-stationary Wafer-less Space.* Brady, *et al.* Issued: May 23, 2023.
- Patent No. 11,771,125. *Concentrated Nutritional or Supplemental Compound for Intestinal, Gut-Brain Axis and Neurobiological Homeostasis through Calibrated Absorption Including Neurotransmitter or Any Equilibrating Compound Release to Treat or Mitigate Disease and Co-morbidities, Particularly Obesity and Malnourishment.* Brady, *et al.* Issued: Oct. 3, 2023.
- Patent No. 11,813,363. *Concentrated Nutritional or Supplemental Compound for Intestinal, Gut-Brain Axis and Neurobiological Homeostasis through Calibrated Absorption Including Neurotransmitter or Any Equilibrating Compound Release to Treat or Mitigate Disease and Co-morbidities, Particularly Obesity and Malnourishment.* (Continuation-in-Part). Brady, *et al.* Issued: Nov. 14, 2023.

Patents (Prior to 2020)

- Patent No. 6,066,296. *Sample addition, reagent application, and testing chamber*. Brady *et al.* Issued: May 23, 2000.
- Patent No. 6,410,337. *Method of platlet [sic] function analysis using platelet count.* Brady *et al.* Issued: Jun. 25, 2002.
- Patent No. 6,417,004. *Enhancing clot detection in activated clotting time and other fibrin endpoint based tests*. Brady *et al.* Issued: Jul. 9, 2002.
- Patent No. 6,872,572. *Method of platelet function analysis using platelet count*. Brady *et al.* Issued: Mar. 29, 2005.

Patents Pending

- *Portable or Stationary Magnetic Antenna for Bidirectional Transmission of Undiminished Communications and Radio Frequency (RF) Signals between Exterior and Interior Spaces.* (#18/088,688) Filed: Dec. 26, 2022.

- *Use of a Sustainable, Modified and Enhanced Aquaculture Limulus Amebocyte Lysate Protein for Detection and Characterization of Infectious Pathogens in Biologic Samples for Patient Screening, Diagnosis and Therapeutic Management.* (#18/131,558). Filed: Apr. 6, 2023.
- *Use of Sustainable, Modified and Enhanced Aquaculture Limulus Amebocyte Lysate Protein and Hemolymph Compounds as a Biologic Broad Spectrum Antimicrobial Therapeutic.* (#18/198,312) Filed: May 17, 2023.
- *Atomic Scale Topical Composition with Enhanced Interstitial Cellular Uptake for Increased Moisturizing, Fluidity, Antioxidant and Radiation Protection, Antimicrobial Cleansing and Therapeutics for Optimal Dermal Integrity and Homeostasis.* (#18/232,877) Filed: Aug. 11, 2023.
- *Customized Ear Compression Device for Keloid Management.* (#18/237,019) Filed: Aug. 23, 2023.
- *Broad-Spectrum Antimicrobial, Biocompatible and Preservative-Free Functionalized Fullerenes Ophthalmic Solution with Reactive Oxygen Species Scavenging and Advanced Targeting, Penetration, and Hydration.* (#18/374,342) Filed: Sept. 28, 2023.
- *Optimized Sustainable Formulation and Manufacturing Process for Animal and Aquaculture Feed for Enhanced Species Health and Longevity.* (#18/380,541) Filed Oct. 16, 2023.

Kepley BioSystems Grants (Since 2015)

- 2022 NSF Phase II SBIR Grant. *A Rapid, Sensitive Pathogen Typing and Antibiotic Sensitivity Test for Bloodstream Infections (COVID-19).* Amount: $1,000,000. Award No. 2212920. Submitted on January 6, 2022; recommended for funding June 2022, with award notice received in December 2022.
- 2021 NSF Phase I SBIR Grant. *A Rapid, Sensitive Pathogen Typing and Antibiotic Sensitivity Test for Bloodstream Infections (COVID-19).* Amount: $255,000. Award No. 2101278.
- 2018 – 2019 NSF Phase I SBIR Grant. *A Novel Horseshoe Crab Device and Approach for a Sustainable Endotoxin Testing Resource.* Amount: $250,000. Award No. 1819562.
- 2016 – 2018 NSF Phase II SBIR Grant (and Supplemental Awards). *A New Sustainable Crustacean Bait.* Amount: $950,000 (including TECP, CAP, REU, RAHSS supplemental grant). Award No. 165896.
- 2015 – NSF Phase I and Phase IB SBIR Grant. *A New Sustainable Crustacean Bait.* Amount: $168,750 (including Phase IB supplemental grant). Award No. 1555752.

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