

EDWARD J. BUTHUSIEM

BERKELEY RESEARCH GROUP, LLC
1800 M Street NW, Second Floor
Washington, DC 20036

Direct: (202) 249-7250
Mobile: (610) 639-1541
ebuthusiem@thinkbrg.com

SUMMARY

Mr. Buthusiem is a Managing Director in the BRG Health Analytics practice and a leader of its Corporate Compliance and Risk Management practice and a co-leader of its Pharmaceutical Valuation Practice. He has over 30 years of experience advising clients on a variety of business, regulatory, operational, intellectual property, litigation, transactional and compliance matters, with particular emphasis in pharmaceutical and medical device product and technology licensing transactions, commercial and strategic transactions, business formation and planning, securities, mergers and acquisitions, compliance, and corporate governance. Since joining BRG in 2013, Mr. Buthusiem has provided expert testimony and support in several litigation matters involving, among other things, the interpretation of licensing and development contracts relating to pharmaceutical and medical device product development, deal structures, valuation, damages calculations and pricing, the scope of commercially reasonable efforts, matters involving bankruptcy and restructuring, fiduciary responsibilities, securities disclosure, adequacy of internal controls and pharmaceutical pre-clinical and clinical development and commercialization.

Mr. Buthusiem has served as a government and court-appointed monitor for entities subject to post-settlement and post-acquisition mandates, including on behalf of the US Department of Justice (DOJ), the Securities and Exchange Commission (SEC) and the Office of Inspector General (OIG) in connection with various civil and criminal actions. Mr. Buthusiem has also served as a court-appointed monitor in connection with the disposition of assets in bankruptcy proceedings as well as an independent third party to oversee the implementation of post-closing obligations primarily involving M&A transactions. He has advised healthcare companies and their legal counsel in implementing Corporate Integrity Agreements (CIAs), as well as negotiating CIA terms with the Department of Justice, the OIG, the SEC, and other governmental agencies. Mr. Buthusiem has also developed and overseen all aspects of compliance programs, including auditing and monitoring; interactions and engagements with healthcare professionals; determining fair market value of goods and services provided by and

offered to physicians; strategic marketing and sales initiatives; transparency reporting; and clinical, research and development, and post-market surveillance.

Prior to joining BRG, Mr. Buthusiem served as General Counsel, Chief Compliance Officer, and Head of Business Development for KaVo Kerr Group (“KKG”), Danaher Corporation’s \$4 billion global dental and medical device business, from 2010 to 2013. His responsibilities included heading the Business Development, Legal, Compliance, Trade Operations and Environmental Health and Safety Departments and overseeing the provision of these services to KKG’s global businesses.

Prior to joining KKG, Mr. Buthusiem was a senior executive at GlaxoSmithKline (“GSK”) from 1990 to 2010. GSK is a \$45 Billion global pharmaceutical, diagnostics and consumer healthcare company. During his tenure at GSK, Mr. Buthusiem served in various senior capacities, including Vice President Global and Strategic Transactions, Senior Vice President, Head of Deal Structuring & General Counsel of R&D and Senior Vice President, Head of Business Development & General Counsel of Vaccines and Senior Vice President & Special Counsel. Among other things, Mr. Buthusiem was responsible for structuring and managing the team that drafted and negotiated product and technology licensing agreements on a global basis as head of Business Development for the Vaccines Division and head of Deal Structuring for Pharma R&D. Mr. Buthusiem also served as a member on numerous project and product management teams which were responsible for the discovery, development and marketing of new drugs and the lifecycle management of existing products and therapeutic franchises. Mr. Buthusiem was also responsible for managing GSK Alliance Management responsible for providing governance and oversight for GSK third party collaborations as well as the development and dissemination of scientific marketing materials to prescribing physicians with overall responsibility for GSK’s Speaker’s Program.

During his tenure at GSK and KKG, Mr. Buthusiem was responsible for directly structuring, valuing, drafting and negotiating, as well as alliance management support for all global transactions, including mergers and acquisitions, joint ventures, pharmaceutical product and R&D licensing and development transactions, pharmaceutical product divestitures, investment banker and broker deals, venture capital partnerships, academic and scientific collaborations, commercial joint ventures, marketing, supply and distribution agreements and a variety of other corporate and commercial transactions. Altogether, Mr. Buthusiem was directly responsible for well over a thousand pharmaceutical, diagnostic and medical device transactions, involving billions of dollars in value. Mr. Buthusiem’s expertise includes, but is not limited to the following types of transactions:

- Product and technology licensing and research collaboration agreements
- Research consortia agreements
- Intellectual property in-licensing, out-licensing, and cross-licensing agreements involving pharmaceutical and medical device products and projects.
- Drug, device, vaccine, and biological product research and development agreements
- Mergers and acquisitions involving businesses, pharmaceutical and medical device products.
- Early-stage drug, device, vaccine, and biological product research development agreements
- Co-promotion and co-marketing agreements
- Manufacturing, supply, and distribution agreements
- Business broker and venture capital investment transactions
- Grant agreements
- Pre-clinical research agreements
- Government contracts
- CRO services agreements
- Clinical trial agreements

Throughout his career both as a Business Development executive and General Counsel, Mr. Buthusiem has advised numerous companies and institutions, their executive management and Boards of Directors on corporate governance issues involving fiduciary duties, and conflicts of interest. Mr. Buthusiem has rendered such advice in connection with the sale of pharmaceutical products to current and former employees and has also advised on similar situations while serving as a director on external Boards. In each case, through his advice Mr. Buthusiem has sought to ensure that any conflicts of interest, whether in the context of transactions or generally, were appropriately addressed and proper safeguards implemented and followed accordingly.

EDUCATION

- J.D. University of Pennsylvania School of Law, 1985
Activities: Member of Jessup Moot Court, 1984-1985 (Captain of the 1985 Team)
- MA University of Brussels, International Economics, 1983
- B.A. Temple University, 1982 (*magna cum laude*)

AWARDS

Recipient of the Temple University 2003 Diamond Achievement Award

Delivered the 2004 Commencement Speech, Temple University College of Liberal Arts

EXTERNAL BOARDS

Chairman, Temple University Board of Visitors for the College of Liberal Arts

Member, Temple University President's Council

Chairman, Temple University Law School Advisory Board for the Center for Ethics and Compliance

EDITORIAL BOARDS

Editor, Compliance and Risk Management eJournal, Legal Scholarship Network

Editor, the Lifesciences Compliance Update

EMPLOYMENT HISTORY

Temple University Beasley School of Law

Adjunct Professor

2015 – Present

Berkeley Research Group, LLC

Managing Director

2013 – Present

Kavo Kerr Group, a Danaher Company

General Counsel, Head of Business Development, Trade Operations and Environmental Health & Safety

2010 – 2013

GlaxoSmithKline plc (formerly SmithKline Beecham plc)

1990 – 2010

Senior Vice President and Special Counsel

2009 – 2010

Senior Vice President, General Counsel of Global R&D and Vaccines Divisions, Head of Business Development (Vaccines) and Head of Deal Structuring (R&D)

2001 – 2009

Vice President & Associate General Counsel, Strategic & Scientific Transactions Department

1995 – 2001

Senior Counsel, Licensing and Commercial Transactions
1990 – 1995

Dickstein, Shapiro & Morin

Associate
1987 – 1990

Fried, Frank, Harris, Shriver & Jacobson

Associate
1985 – 1987

TESTIFYING EXPERIENCE

Case No. 2020-0953-SG

AbbVie Endocrine Inc. v. Takeda Pharmaceutical Company Limited
Court of Chancery of the State of Delaware

ICC Case No. 25658/pdp

Ambio Inc. v. Sandoz Inc.
International Court of Arbitration of the International Chamber of Commerce

Civil Action No. 19-2300-RGA

Ares Trading S.A. v. Dyax Corp.
United States District Court for the District of Delaware

Index No. 657269/2017

Array Biopharma Inc. v. Astrazeneca AB
Supreme Court Of The State Of New York

Case No. 20-741-RGA

Artoss, Inc., v. Artoss GmbH, Thomas Gerber and Walter Gerike
United States District Court for the District of Delaware

Consolidated Case No. 1:14-cv-03547-RMB-KMW

AstraZeneca Pharmaceuticals LP et al. v. Sandoz Inc. et al.
United States District Court for the District of New Jersey

Consolidated Case No. 1:15–CV–06039-RMB-KMW

AstraZeneca Pharmaceuticals LP v. Teva Pharmaceuticals USA, Inc. and Innopharma Licensing, LLC
United States District Court for the District of New Jersey

Case No. 2389/MK

Biocryst Pharmaceuticals, Inc. v. Seqirus UK LTD.
International Chamber of Commerce

Case No. 30-2019-01119045-CU-CO-CJC

BLS Pharma, Inc., v. Inovio Pharmaceuticals, Inc. and Genetronics, Inc.
Superior Court of The State of California for the County of Orange

ICC Case No. 25357/AZ

Braeburn, Inc. v. Camurus AB
International Court of Arbitration of the International Chamber of Commerce

Adv. Proc. No. 23-50367 (JKS)

Clovis Oncology, Inc. et al., v. TOP IV Talents, LLC, TAO Talents, LLC, TOP IV SPV GP, LLC, and John Doe Entities 1-100
United States Bankruptcy Court for the District of Delaware

Index No. 651597/2018

Doctors Allergy Formula, LLC v. Valeant Pharmaceuticals International
Supreme Court of the State of New York

Arbitration No. 27107/AB

EOC Pharma (Hong Kong) Limited v. Aadi Bioscience, Inc.
International Court of Arbitration of the International Chamber of Commerce

C.A. No. 2:21-cv-3619-BHH

FirstString Research, Inc., v. Regranion, LLC, Gautam Ghatnekar, and Stefanie Cuebas
The United States District Court for the District of South Carolina

Case No. 111CV203554

Glenridge Pharmaceuticals LLC. v. Questcor Pharmaceuticals, Inc.
Superior Court of the State of California for the County of Santa Clara

Derivative Action 57303-09-16

Gur Tzemach and YAAS Investments Ltd. V. Teva Pharmaceutical Industries, Ltd.
Israel Central District Court

C.A. No. 20-cv-00881-RGA

Hemostemix, Inc., v. Accudata Solutions, Inc. and Aspire Health Science, LLC
The United States District Court for the District of Delaware

Index No. 652056/2013

Highland Crusader Offshore Partners v. Celtic Pharma Phinco B.V.
Supreme Court of the State of New York County of New York

ICC Case No. 25372/MK

I-MAB vs. Tracon Pharmaceuticals, Inc.
International Chamber of Commerce

Case No. 16 Civ. 3241 (ER) (JLC)

Impax Laboratories, Inc. v. Turing Pharmaceuticals AG

United States District Court for the Southern District of New York

Case Nos. 400001/2017, 400008/2017, 40016/2018

In re: Opioid Litigation: The County of Suffolk, New York v. Purdue Pharma, L.P., The County of Nassau, New York v. Purdue Pharma L.P., The People of the State of New York v. Purdue Pharma, L.P.

Supreme Court of the State of New York County of Suffolk

Case No. C41916

Barry Staubus, et al. v. Purdue Pharma, Inc. the Purdue Frederick Company; Mallinckrodt LLC; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc., et. al
Circuit Court for Sullivan County, Kingsport, Tennessee

Case No. 17-MD-2804

In Re National Prescription Opiate Litigation

United States District Court for Northern District of Ohio

Case No. 13-md-2460

In Re Niaspan Antitrust Litigation

United States District Court for Eastern District of Pennsylvania

No. 1425030457

James B. Sherwood v. Belmond Ltd.

JAMS Commercial Arbitration

ICC Case No. 25598/PDP

Lavvan, Inc. v. Amyris, Inc.

International Chamber of Commerce New York

ICC Case No. 23681/MK

LOCL Pharma, Inc. (D.b.a. Charleston Laboratories Delaware) v. Daiichi Sankyo Company Limited

International Court of Arbitration of the International Chamber of Commerce

Case No. 1100110754

Lyell Immunopharma, Inc. v. Pact Pharma, Inc.

Supreme Court of the State of New York

Case No. 01-19-0003-3950

NantCell, Inc.; and Immunotherapy NANTibody, LLC v. Sorrento Therapeutics, Inc.; and Henry Ji

American Arbitration Association

Claim No. HC 2015 003978

Norgine B.V. v. Salix Pharmaceuticals, Inc.
High Court of Justice, Chancery Division (UK)

Case No. 1:13-cv-01475

Opengate Capital Group LLC v. Thermo Fisher Scientific Inc.
United States District Court for the District of Delaware

Case No. 22-10995 (LSS)

PhaseBio Pharmaceuticals, Inc., v SFJ Pharmaceuticals X LTD.
The United States Bankruptcy Court District of Delaware

Case No. ARB106-18-CHB

PT Otto Pharmaceutical Industries v. PT Abbott Indonesia
Singapore International Arbitration Center

Case No. 3:16-cv-0132

SEC v. Edward J. Kosinski
United States District Court for the District of Connecticut

Index No. 650773/2015

Southern Advanced Materials, LLC v. Robert S. Abrams, et Al.
Supreme Court of the State of New York

Docket Number 650908/14

Sybron Canada Holdings, Inc. v. Niznick
Supreme Court, New York County

AAA Case No. 01-15-0006-0746

Torreya Partners LLC v. Mimetogen Pharmaceuticals, Inc.
American Arbitration Association

Case No. H-18-2871

Veterans First Medical Supply, LLC. v. Tactile Systems Technology, Inc.
United States District Court for the Southern District of Texas

No. 19-cv-01760-PJS-TNL

Vascular Solutions LLC v. Medtronic, Inc.
United States District Court for the District of Minnesota

Case No. 01-20-001-6913

Vetoquinol USA Inc. v Ampharmco, LLC
American Arbitration Association

PUBLICATIONS

1. Chapter 4, “Intellectual Property Protections for Medical Devices,” Bringing Medical Devices to Market, American Bar Association (2021).
2. “Compliance Officers Take Note: CMS and OIG Propose New Rules Relating to Anti-Kickback Regulations,” *BRG Healthcare client alert*, October 24, 2019
3. “DOJ Antitrust Division Now Considers Compliance at the Charging Stage,” *BRG Healthcare client alert*, July 29, 2019
4. “Compliance Officers Take Note: DOJ Releases New Guidance on Corporate Compliance Programs,” *BRG Healthcare client alert*, May 3, 2019
5. “New FCPA Policy Credits Effective Compliance Programs,” *BRG*, December 5, 2017
6. “Telia’s Compliance Program Efforts Dodge Monitorship Requirement,” *BRG Healthcare client alert*, September 29, 2017
7. “DPAs and NPAs Are on the Rise,” *Corporate Compliance Insights*, July 28, 2017
8. “SPIF at Your Own Risk,” *BRG Healthcare client alert*, March 8, 2017
9. “Insights from the DOJ: Evaluation of Corporate Compliance Programs,” *BRG Healthcare client alert*, March 6, 2017
10. “DOJ Criminal Division Launches New FCPA Pilot Program on Self Disclosure,” *BRG*, April 2016
11. “Why Temple Law School Launched a Center for Compliance and Ethics,” *The Temple 10-Q*, March 16, 2016
12. “Using Data Analytics and Enhanced Monitoring Techniques to Avoid Government Enforcement and Individual Liability,” *Pharmaceutical Compliance Monitor*, July 16, 2015
13. “Drug Serialization Trends and Developments,” *Pharmaceutical Compliance Monitor*, May 6, 2015
14. “Global Investigations and Compliance Services Enforcement Roundup,” *BRG newsletter*, March 2015
15. “Global Investigations and Compliance Services Enforcement Roundup,” *BRG newsletter*, February 2015
16. “Global Investigations and Compliance Services Enforcement Roundup,” *BRG newsletter*, January 2015
17. “Global Investigations and Compliance Services Enforcement Roundup,” *BRG newsletter*, December 2014

18. “Regulatory and Compliance Implications of Orphan Drugs,” *Pharmaceutical Compliance Monitor*, November 24, 2014
19. “Global Investigations and Compliance Services Enforcement Roundup,” *BRG newsletter*, November 10, 2014
20. “Recent Trends in Whistleblower Protection under Dodd–Frank,” *Pharmaceutical Compliance Monitor*, October 20, 2014
21. “Global Investigations and Compliance Services Enforcement Roundup,” *BRG newsletter*, October 2014
22. “Global Investigations and Compliance Services Enforcement Roundup,” *BRG Newsletter*, September 2014
23. “Global Investigations and Compliance Services Enforcement Roundup,” *BRG newsletter*, August 2014
24. “Global Investigations and Compliance Services Enforcement Roundup,” *BRG newsletter*, July 2014
25. “Global Investigations and Compliance Services Enforcement Roundup,” *BRG newsletter*, May 2014
26. “Global Investigations and Compliance Services Enforcement Roundup,” *BRG newsletter*, April 2014
27. “Compliance Officers: Three Common Mistakes to Avoid,” *Pharmaceutical Compliance Monitor*, March 19, 2014
28. “Six Strategies to an Effective Risk Assessment and Mitigation Program,” *Pharmaceutical Compliance Monitor*, January 8, 2014
29. “Here Comes le Soleil Français: The French Sunshine Act Has Arrived,” *Corporate Compliance Insights*, July 3, 2013
30. “PODs: Proceed with Extreme Caution,” *Orthoworld*, June 10, 2013
31. “Five Steps to Sunshine: Strategies for Complying with CMS’ Reporting Requirements,” *Orthoworld*, May 9, 2013
32. “A Practical Guide to Anti-Corruption Compliance for the Medical Device Industry,” *Pharmaceutical Compliance Monitor*, April 19, 2013
33. “Here Comes the Sun,” *Pharmaceutical Compliance Monitor*, March 18, 2013

SEMINARS AND SPEAKING ENGAGEMENTS

Pharmaceutical Compliance Congress
April 16-18, 2019

19th Annual Pharmaceutical and Medical Device Compliance Congress
November 7-9, 2018

Legal Issues in International Healthcare and Pharmaceuticals
October 18, 2018

Pharmaceutical and Medical Device Compliance Congress
November 6-8, 2017

Pharmaceutical Compliance Congress
April 26-28, 2017

HCCA Annual Compliance Institute
March 26-29, 2017

Open Payments 2016 Program Year
March 8, 2017

Sixth Annual West Coast Compliance Congress
November 15 – 16, 2016

Current Trends in Compliance and Enforcement
April 7, 2016

Pharmaceutical Compliance Congress
January 26 – 27, 2016

Current Trends in Ethics and Compliance Law
November 9, 2015

DTA Business Essentials: Determining Fair Market Value for the Dental Industry
August 4, 2015

Pharmaceutical Compliance Congress
March 3 – 4, 2015

Fifth Annual West Coast Compliance Congress
November 13 – 14, 2014

Forum on Transparency and Aggregate Spend
August 18, 2014

FMV of HCP and Investigator Payments
May 20 – 21, 2014

Instruments Compliance and Ethics Synergy Conference
April 14, 2014

Sunshine Act 3.0

March 20, 2014

**10th Annual Regulatory and Compliance Congress for Medical Device and
Diagnostics**

February 25 – 26, 2014

Latin America Compliance Conference

February 11 – 13, 2014

11th Annual Pharmaceutical Compliance Congress

January 28 – 29, 2014

Forum on Sunshine and Aggregate Spend

August 19 – 21, 2013

Here Comes the Sun

February 28, 2013