Appendix A



John C. Staines, Jr. Director & Principal

1200 19th Street, NW Washington, DC 20036

Phone: 202-481-8524 Fax: 202-973-2401 Email: john.staines@naviganteconomics.com

EDUCATION

- 1990 M.B.A., Business Economics and Finance, University of Chicago
- 1984 M.P.M., Public Policies Toward Business, University of Maryland
- 1982 B.A., Economics, University of Maryland

PROFESSIONAL POSITIONS

- 2010-Present <u>Director & Principal, Navigant Economics</u> Manage and conduct economic, financial and quantitative analyses related to commercial litigation and regulation.
- 2000-2010 <u>*Principal, LECG, LLC*</u> Managed and conducted economic, financial and quantitative analyses related to commercial litigation and regulation.
- 1996-2000 <u>Principal, Putnam, Hayes & Bartlett, Inc.</u> Managed and conducted economic, financial and quantitative analyses related to commercial litigation and regulation.
- 1990-1995 <u>Associate, Putnam, Hayes & Bartlett, Inc.</u> Conducted economic, financial and quantitative analyses related to commercial litigation and regulation.
- 1985-1988 <u>Associate, Heiden Associates, Inc.</u> Performed economic impact studies of proposed environmental and health regulations, economic analyses of antitrust issues, and statistical analyses of product safety risk.
- 1984 <u>Analyst, U.S. Environmental Protection Agency</u>, Office of Policy Analysis. Performed economic and risk studies of proposed environmental regulation of hazardous wastes.

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RECENT EXPERT TESTIMONY

- Acrux DDS PTY Ltd. & Acrux Ltd v. Kaken Pharmaceuticals Co., Ltd., and Valeant Pharmaceuticals International, Inc., U.S. Patent and Trademark Office, Patent Trial and Appeal Board, Case IPR2017-00190, U.S. Patent No. 7,214,506, 2017. (Expert Witness Report and Deposition Testimony.)
- Hospira, Inc. v. Sylvia Mathews Burwell, Secretary, U.S. Department of Health and Human Services; Dr. Margaret Hamburg, Commissioner, U.S. Food and Drug Administration; Par Sterile Products, LLC (Intervenor-Defendant), U.S., District Court for the District of Maryland, Case No. 8:14-cv-02662-GJH, 2014. (Expert Witness Affidavits.)
- SmithKline Beecham Corp., et al., v. Mylan Laboratories, Inc., et al., U.S., District Court for the District of New Jersey, Civ. Action No. 07-2939 (JAP), 2007. (Expert Witness Declaration.)
- *J.E. Pierce Apothecary, Inc., et al., v. Harvard Pilgrim Healthcare, et al.,* U.S., District Court for the District of Massachusetts, Civ. Action No. 98-CV-12636-RCL, 2003. (Expert Witness Declaration and Deposition Testimony.)

CONSULTING ACTIVITIES

- Experienced in applying microeconomic, financial, and other quantitative tools and theories in the areas of commercial litigation and public policy. Specific areas of experience include the economic analysis of markets and competitive effects of various business practices, as well as valuation of economic damages in intellectual property, antitrust, and other types of commercial litigation, as well as the impact of dumped and subsidized imports in international trade cases and economic impact and risk assessment in the context of product liability litigation and regulatory rulemakings.
- Work has typically included designing and directing data and other economic analyses, drafting expert reports, and evaluating analyses submitted by other experts.
- A large proportion of these consulting assignments has involved economic issues arising in the Pharmaceutical industry. Other industries studied include: Computers and Peripherals, Software Operating Systems, Applications Software, Enterprise Resource Planning Systems, Telecommunications, Steel, Coastal Oil Shipping, Oil Refining Equipment, Gasoline wholesaling and retailing, Chemicals, Plastics Additives, Wood-Panel Products, Uranium Mining and Enrichment, Crushed Stone, Athletic Footwear, Automobiles, Paint Manufacture, and Third Class Mail Delivery.

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Pharmaceutical Industry Cases

Analyzed economic, statistical, and financial issues associated with pharmaceutical-related cases involving allegations of patent infringement, antitrust violations, proposed regulations, and various other commercial claims, as well as regulatory compliance. Specific projects include the following:

Pharmaceutical Patent Infringement

- Estimated lost profit and reasonable royalty damages associated with alleged sales of infringing drugs.
 - Zegerid[®] (ompeprazole) Ulcers and Gastroesophageal Reflux Disease ("PPI")
 - Epivir[®] (lamivudine) AIDS treatment
 - Nitro-Dur[®] (nitroglycerin patch) Angina
 - Humulin[®] (proinsulin) Type II Diabetes
 - Humatrope[®] (somatropin) Human Growth Hormone
- Analyzed the extent and economic sources of "commercial success" for brand name drugs as possible secondary indicia of "nonobviousness" in several Hatch-Waxman patent infringement litigations brought against prospective generic entrants and *Inter Partes* reviews sought by prospective generic entrants before the Patent Trial and Appeal Board of the U.S. Patent & Trademark Office.
 - Jublia® (efinaconazole) Toenail Onychomycosis
 - Omidria® (ketorolac/phenylephrine) Cataract Surgery Dilation and Pain Reliever
 - Minivelle® (estradiol transdermal patch) Menopause "Hot Flashes"
 - Colcrys[®] (colchicine) Gout
 - Megace[®] ES (megestrol) Appetite Stimulant for AIDS Patients
 - Trilipix[®] (choline fenofibrate) Low HDL Cholesterol / High Triglycerides
 - Yaz[®] (drospirenone / ethinyl estradiol) Oral Contraceptive
 - Aplenzin[®] (bupropion HBr) Depression & Anxiety Disorder ("SSRI")
 - Ritalin LA® (methylphenidate) Attention Deficit & Hyperactive Disorder ("ADHD")
 - Xyzal® (levocetirizine) Non-Sedating Antihistamine for Allergic Rhinitis
 - Prevacid[®] (lansoprazole) Ulcers & Gastroesophageal Reflux Disease ("PPI")
- Analyzed economic issues and survey data to determine whether a generic entrant's non-infringing use would be "insubstantial" in the context of a Hatch-Waxman "Section 8 Carve-Out": Actos® (pioglitazone) type II diabetes.
- Analyzed possible irreparable harm, balance of hardships, and economic impact on the public interest of proposed Temporary Restraining Orders and/or Preliminary Injunctions on allegedly infringing product sales.
 - Precedex[®] (dexmedetomidine) Sedative for Intubation and Surgery
 - Nuvigil[®] (armodafinil) Excessive Sleepiness
 - Seasonique[®] (levonorgestrel / ethynil estradiol) Oral Contraceptive

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- Ritalin LA[®] (methylphenidate) Attention Deficit & Hyperactive Disorder ("ADHD")
- Glucophage[®] (metformin) Type II Diabetes
- Tessalon[®] (benzonatate) Cough Suppressant
- Various Unapproved ("DESI") Topical Pharmaceutical Treatments
- Paxil CR[®] (paroxetine) Depression & Anxiety Disorder
- Ethyol[®] (amifostine) Ovarian/Neck/Head Cancer Chemo/Radiation side effects

Pharmaceutical Antitrust/Competition

- Alleged anticompetitive "reverse-payment" patent settlement: Lidoderm® (lidocaine patch) pain medication
- Antitrust counterclaim alleging price bundling and exclusive dealing: Epogen®/Aranesp®, Neupogen®/Neulasta® anemia and neutropenia treatments
- Alleged predation involving brand firm's launch of an "authorized generic": Macrobid[®] (nitrofurantoin monohydrate macrocrystals) urinary tract infections
- Potential antitrust counterclaims associated with brand firm's actions to forestall generic competition: Paxil CR[®] (paroxetine) depression & anxiety disorder
- Competitive effects and potential antitrust implications of the proposed terms of a bulk API supply contract in the market for generic Augmentin[®] (amoxicillin/clavulanic acid).
- Market definition and competitive impacts of a proposed merger under FTC review in the relevant pharmaceutical markets for Enbrel[®] (etanercept) and Kineret[®] (anakinra), biological treatments for rheumatoid arthritis.
- Adequacy of competition and prospective effects of entry in various pharmaceutical controlled substance markets as part of five Drug Enforcement Administration hearings on the proposed registration of new bulk manufacturers and/or importers of:
 - opium / concentrate of poppy straw (oxycodone, hydrocodone, morphine, codeine)
 - cocaine for use as a local anesthetic
 - methylphenidate for treatment of attention deficit disorder.

Pharmaceutical Commercial Damages

- Generic lost profits from delayed FDA approval and generic exclusivity forfeiture due to flaws in a contract research organization's bioequivalence studies: Zoloft[®] (sertraline) depression & anxiety disorder; Zofran ODT[®] (ondansetron) cancer-related nausea; Avelox[®] (moxifloxicin) antibiotic.
- Financial valuation of a refractory chronic gout drug in relation to a proposed temporary restraining order to delay a proposed financial transaction and motion to put owner into receivership.

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- Overcharges to private insurers and State governments associated with alleged overreimbursement of drug costs due to inflated Average Wholesale Prices ("AWPs"): Epogen®/Aranesp®, Neupogen®/Neulasta® anemia and neutropenia treatments.
- Lost profit and shareholder diminution damages due to a U.S. generic firm's alleged failure to purchase various finished dose products from a Jordanian pharmaceutical company per terms of the parties' agreement: Various generic drugs.
- Impact of generic entry on an acquired brand company's financial valuation: Ifex[®] /Mesnex[®] (ifosfamide/mesna) testicular cancer.
- Overcharge damages due to a PBM's alleged price-fixing of insurance reimbursement rates for drug prescriptions applied to a class of independent pharmacies.
- Stock market event study of the financial impact of an FTC investigation of drug products marketed by a pharmaceutical acquisition target. Skelaxin[®] (metaxalone) muscle relaxant.
- Shareholder value damages allegedly associated with overpayment for a generic biopharmaceutical firm acquisition.
- Variety of analyses and research activities associated with a license dispute involving U.S. sales of Epogen[®] and Procrit[®] (epoetin alfa) anemia.
 - Methodologies to track licensor/licensee sales by therapeutic indication;
 - Methods to reimburse profits on cross-indication sales;
 - Lost profits due to allegedly delayed FDA approval;
 - Financial valuation of market segments.
 - Detailed analysis of Medicare reimbursement claims data
 - Estimation of price erosion due to competition from licensee.
- Bankruptcy damages of a large pharmaceutical wholesaler (FoxMeyer Drug) allegedly caused by the flawed implementation of a new management information system.
- Lost profit/value damages associated with foregone development opportunities for drugs to treat obesity, anxiety, depression, insomnia, Alzheimer's, and benign prostate hypertrophy, due to massive product liability claims allegedly caused by the Defendant.
- Financial analyses to support a fairness opinion for settlement of class action claims associated with adverse side effects. Redux[®] (dexfenfluramine) diet drug.
- Valuation analyses to support a fairness opinion for settlement of a shareholder lawsuit: ReoPro[®] (abciximab) treatment for patients undergoing percutaneous transluminal coronary angioplasty (PCTA) to treat coronary artery disease.
- Lost royalty damages for a prospective HIV/AIDS and hepatitis B drug that Defendant allegedly failed to develop.
- Lost royalty damages for a prospective monoclonal antibody-based drug to treat asthma and allergic rhinitis that Defendant allegedly had not timely developed. Xolair[®] (omalizumab).

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- Lost royalty damages in the U.S., Europe, and East Asia due to the alleged failure of the licensee to obtain regulatory approval for a Hepatitis B vaccine and a cancer drug.
- Lost profit and royalty damages due to the licensee's alleged failed to supply bulk product and maintain patents for a synthetic hepatitis B and C drug in East Asia.

Pharmaceutical Consulting

- Assisted in a pharmacoeconomic analysis used to formulate a client's future marketing strategy for promoting new uses of current and prospective pacemaker technologies.
- Developed mathematical programming model to generate profit-maximizing production strategies for a pharmaceutical company's jointly-produced plasma fractions products.

Economic/Competition Analysis – Other Industries

Developed economic and supporting quantitative analyses of the level, nature, and conditions of industry competition in a variety of markets in antitrust and other legal/regulatory contexts. Evaluated the likely economic impact of proposed government regulation of industry in terms of prices, demand, investment, entry and exit, industry structure, employment, etc. Specific projects include the following:

- Analyzed competition issues raised in an antitrust counterclaim involving Standardbred Harness Horseracing.
- Performed various analyses of company financial data, operations data, and survey results to analyze pyramid scheme allegations regarding the U.S. Operations of a Multi-Level Marking firm manufacturing and selling health foods.
- Analyzed ARCO franchisee claims of unfair competition associated with British Petroleum's pricing of wholesale gasoline supply.
- Conducted economic analyses related to proposed class certifications in litigations involving price-fixing and monopolization allegations associated with the sale of:
 - plastics additives used in the manufacture of products incorporating poly-vinyl chloride ("PVC") and certain engineering resins
 - organic peroxides used in the manufacture of various types of plastic products
 - computer operating and applications software
- Assessed the validity of potential antitrust claims against the dominant supplier of
 personal computer operating systems, internet browser software, and applications
 software arising from the company's alleged attempts to impede the adoption of a
 competitor's internet-based "middleware" platform software that threatened the
 incumbent's monopoly power.
- Analyzed price pass-through of alleged monopoly surcharges associated with certification of a class of indirect purchasers claiming damages from the purchase of

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the defendant's computer operating system, word processing and spreadsheet software.

- As part of a price discrimination case, analyzed the economics of manufacturer-retail agency relationships in the cellular telephone industry, including determination of the attributes of effective retail agents and the impact of product life-cycles on the optimal retail channel.
- Performed statistical analyses of product differentiation and market delineation in the luxury automobile market in support of a price discrimination case involving the "gray market" for Mercedez Benz automobile parts.
- Performed economic analyses of the competitive, price, and financial impacts of proposed environmental and health regulations affecting manufacturers and customers various products.
 - Formaldehyde
 - Methylenedianiline
 - Audio/video/computer Magnetic Tapes & Disks
 - Crushed Stone Aggregate
- Performed analyses in support of a theoretical and empirical study of the natural monopoly rational for prohibiting the private delivery of third-class addressed mail.
- Performed industry analyses of the economic incentive effects in the Paint Industry of imposing a waste-end tax on the land disposal of hazardous wastes as a supplemental source of financing for the U.S. EPA's "Superfund" program.

Damages Analysis – Other Industries

Supervised calculation of damages based on analysis of product supply and demand, product lifecycles, prices, market share, entry and exit, first-mover effects, costs of capital, internal rates of return, opportunities for mitigation, stock price changes, and other economic factors. Specific work experience includes the following:

- Analyzed lost profit and direct cost damages sustained due to installation of allegedly
 defective refractory lining material in regenerator and third stage separator equipment
 at the FCC units of various oil refineries.
- Estimated lost repair profit damages associated with alleged infringement of design and utility patents for portable data terminals used by delivery firms and the US Postal Service to scan and store package delivery information.
- Estimated damages incurred by the owner of certain FCC wireless licenses in California that resulted from an accounting firm's alleged misrepresentation of a licensee's financial condition.
- Performed valuation of a wireless telecommunications company in Venezuela to estimate damages associated with the alleged failure of a U.S. telecommunications company to purchase shares in compliance with a put option agreement.

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- Estimated the appropriate compensation due to a U.S. coastal shipping company associated with the alleged U.S. Government "taking" of the company's oil tank barges and other capital assets that resulted from the double-hull provisions of the 1990 Oil Pollution Act.
- Calculated damages generated by alleged breaches associated with the provision of consulting services to upgrade a management information system in the computer distribution industry.
- Calculated lost profit damages associated with a telecommunications company's alleged breach of a marketing contract with a wireless telecommunications company.
- Calculated damages to royalty owners of a CO₂ gas field resulting from alleged underpricing of well-head CO₂ and alleged tariff overcharges for pipeline transportation to enhanced oil recovery fields.
- Calculated lost profit and lost investment damages in a European breach-of-contract case associated with a patent for a new running shoe technology.
- Evaluated the theoretical framework for estimating damages in multiple breach-ofcontract cases in the electric utility industry.
- Drafted report on a theoretical framework appropriate for estimating damages as part of defendant's submission to a European Tribunal, and evaluated plaintiff's damages estimates in a breach-of-contract case involving wood panel presses.
- Analyzed costs and estimated lost profit margins in support of expert testimony involving alleged infringement of patents related to X-Y pen plotters.

International Trade

Estimated the magnitude of import dumping margins and the resulting injury of dumped and subsidized imports to the domestic industry. Met with Department of Commerce staff to argue for modifications in margin estimates. Analyzed International Trade Commission questionnaire responses. Prepared exhibits for hearings. Evaluated and developed economic models of domestic industry impacts of unfairly traded imports.

- Developed economic arguments to support briefs and expert economic testimony in a dumping and subsidy case involving U.S. imports of seamless steel pipe from Argentina, Brazil, Germany, and Italy. Evaluated the applicability of ITC's computer model measuring injury to the domestic industry. Identified conceptual flaws in opposing experts' use of an oligopoly model to estimate price effects of imports.
- Performed a variety of economic, financial, and statistical analyses in a dumping investigation of U.S. imports of natural and enriched uranium from the former Soviet Union. Estimated less-than-fair-value margins based on construction of average costs. Developed market model of world uranium trade to estimate injury to the domestic industry and to simulate price impacts of alternative import restriction mechanisms proposed in Suspension Agreement negotiations.
- Analyzed and identified statistical flaws in ITC's econometric model of the domestic price and quantity impact of unfairly traded potato imports from Canada.

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Product Liability/Risk Assessment

- Developed a statistical model used by industry to assess the risk of injury and death associated with All Terrain Vehicles (ATVs). Performed risk and cost-benefit analyses of various regulatory proposals considered by the U.S. Consumer Product Safety Commission. Evaluated risk of injury and death to specific plaintiffs in support of expert testimony in ATV product liability litigation.
- Performed statistical analyses of the risk of injury and death associated with chain saws and radial arm saws in support of expert testimony in regulatory hearings and product liability litigation.
- Assisted in estimating reduction in health risks associated with proposed regulations limiting airborne emissions from industrial boilers.

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