Paul Abato, Ph.D.

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SUMMARY

Dr. Abato is a Ph.D. Medicinal Chemist with over 25 years of experience in the discovery and development of novel human therapeutics in the areas of cancer, anti-infective, anti-inflammatory, and neurodegenerative diseases. He has been involved in all aspects of drug research and development, from synthesis/purification, *in vitro* and *in vivo* testing (efficacy, pharmacokinetics, and pharmacodynamics), dosing routes, drug formulation, stability studies, and the management of CROs. Dr. Abato co-authored a pre-IND proposal for SMA that received a favorable review by the FDA.

He has contributed to the discovery of five preclinical candidates for Multiple Sclerosis, Arthritis, and Spinal Muscular Atrophy. Dr. Abato was awarded the Heroes of Chemistry Award by the American Chemical Society in August 2019 for his contribution to the antibiotic NUZYRA (omadacycline).

Dr. Abato has testified in high-stakes litigation cases at the International Trade Commission on two occasions, the High Court of Malaysia on three occasions, and in Federal and State Courts. He has been deposed nine times and has been engaged as an expert in pharmaceutical-related cases pertaining to patent validity and infringement, ANDA/Paragraph IV disputes, trade secret misappropriation, trademark infringement, and product liability.

He has consulted for H3-Biomedicine in efforts to develop drugs for cancer, where he directed the radiolabeled syntheses of active pharmaceutical ingredients (API) for pharmacokinetic studies as well as the design of stability studies and formulation in support of CMC efforts. He has also consulted for the Bill and Melinda Gates Medical Research Institute in the development of new drug combinations to be used in clinical trials against resistant TB infections.

EDUCATION

Rhode Island College, Providence, RI — B.A., Chemistry (Minor in Biology), May 1996
Awarded Excellence in Organic Chemistry by the American Polymer Society

Brown University, Providence, RI — Ph.D., Chemistry, February 2002
Advisor: Prof. Christopher T. Seto
Thesis: *The Development of A New Class of Protease Inhibitors and EMDee: A New High-Throughput Enzymatic Method For The Determination of Enantiomeric Excess*

Brown University, Providence, RI (6/1996–2/2002)

Ph.D. Candidate, Department of Chemistry; PI: Christopher T. Seto Ph.D.

- Optimized a novel class of protease inhibitors based on a cyclohexanone core.
- Developed a protocol for the synthesis of cyclohexanone-based protease inhibitors on solid support.
- Designed and synthesized a 400-member library of cyclohexanone inhibitors on solid support.
- Developed an enzymatic assay for high-throughput screening of catalysts for asymmetric reactions (see EMDee publication).
- Developed methodology to conduct assays in a 384-well format to assess inhibition constants for a library of peptidomimetic compounds against various proteases such as cathepsin B, plasmin, papain, trypsin, thrombin, and kallikrein.

- Monitored reactions by TLC, IR, 1H NMR, 13C NMR, and HPLC. Purification by flash chromatography, crystallization, distillation, separation of diastereomers by HPLC and enantiomers by both chiral-GC and chiral-HPLC. Analysis of final compounds by 1H NMR, 13C NMR, 2D NMR, and MS. Proficient with enzymatic assays and gel electrophoresis.

AWARDS

- **Heroes of Chemistry Award**, American Chemical Society, 2019 — for contributions to the antibiotic drug NUZYRA
- **Excellence in Organic Chemistry**, American Polymer Society, 1996

PHARMACEUTICAL INDUSTRY EXPERIENCE

Paratek Pharmaceuticals, Boston, MA (8/2002–6/2013)

Biotech developing tetracycline therapeutics for anti-infective, anti-inflammatory, and neurodegenerative diseases.

Principal Scientist/Project Coordinator (Project Coordination/Lab Work ~60%/40%) 01/2009–06/2013

- Project Coordinator for the Spinal Muscular Atrophy (SMA) program in preclinical development.
- Co-authored a pre-IND application for the intrathecal administration of the clinical candidate for SMA (reviewed by the FDA 1/23/13).
- Responsible for design and development of intrathecal (IT) and intracerebroventricular (ICV) continuous and bolus formulations and dosing protocols for mice, rat, and monkey studies.
- Designed and conducted stability studies and deoxygenated formulation studies for continuous dosing efficacy studies compatible with Alzet osmotic pumps.
- Worked with cross-functional teams in cell biology, pharmacology, process chemistry, and vendors that supported *in vivo* efficacy studies, DMPK, and GLP toxicity studies.
- Responsible for synthesis of new compounds and lead optimization of medicinal chemistry efforts for SMA.
- Outsourced and managed preclinical efficacy/PK testing of three compounds at multiple CROs to facilitate preclinical toxicity and further PK analysis of the clinical candidate in mice, rat, and monkey.
- Contributed to grant writing for NIH and FSMA grants.
- Developed a new antibacterial for bacterial-resistant respiratory infections in cattle for Elanco; delivered an efficacious antibacterial compound for subcutaneous bolus dosing that would not cause tissue staining.
- Managed one direct report.

Senior Scientist (Project Coordination/Lab Work ~30%/70%) 01/2006–01/2009

- Worked on areas of anti-inflammation and functioned as the project coordinator for SMA.
- Responsible for synthesis of new derivatives, lead optimization, and analysis of results from outsourced and in-house *in vitro* studies, whole cell, pharmacology, and *in vivo* studies.
- Worked with cross-functional teams in cell biology, pharmacology, process chemistry, as well as vendors that supported *in vitro* and *in vivo* efficacy studies.
- Developed HPLC purification methods for large-scale (6" diameter column) epimer separation of novel tetracycline derivatives previously not possible.
- Managed one direct report.

Scientist II (01/2003–01/2005)

- Discovered and developed novel tetracyclines for the treatment of multiple sclerosis (MS) in collaboration with Serono; delivered three validated preclinical tetracycline leads for MS.

- Developed drug formulation procedures that reduced tolerability issues when dosing IP and IV, thereby enabling a wider therapeutic window with which to compare compounds using experimental autoimmune encephalomyelitis (EAE) mouse efficacy studies. Also developed improved formulations for sub-Q and IM dosing.
- Responsible for synthesis of new derivatives, lead optimization, and analysis of results from *in vivo* efficacy studies.
- Worked with cross-functional teams in cell biology, pharmacology, and process chemistry.
- Built a micro reactor to develop an oxidation assay to elucidate the structure-activity relationship for tetracycline oxidation/tissue staining, a potentially negative aspect of some tetracyclines. The assay results correlated with tissue staining *in vivo*.

Scientist I (08/2002–01/2003)

- Contributed to the development of preclinical candidates for hospital- and community-acquired severe bacterial infections.
- Optimized synthetic methods and developed purification protocols for two key tetracycline intermediates on a 100g scale, removing a significant bottleneck in the production of tetracycline derivatives.
- One lead compound, omadacycline, was subsequently FDA-approved (2018) as NUZYRA; a second completed Phase I trials.

Eikos Inc., Franklin, MA (2/2002–8/2002)

Biotech/material science company developing antimalarial drugs and incorporation of carbon nanotubes into polymers.

Scientist I

- Managed all aspects of chemistry at Eikos. Conducted polymer production reactions using a 50L reactor.
- Developed a solid-phase organic synthesis protocol for the production of aminoquinoline antimalarials in support of an SBIR grant.
- Managed three direct reports.

PHARMACEUTICAL CONSULTING EXPERIENCE

Ionic Alliance Group (8/2022–4/2023)

- Provided summary of preclinical studies relating to a potential mechanism of action for an anticancer drug product.

The Bill and Melinda Gates Medical Research Institute (12/2019–3/2022)

- Provided support in the development of drug combinations consisting of Bedaquiline, Pretomanid, Sutezolid, and Delamanid to treat resistant TB infections.

CraniUS LLC (12/2021–4/2022)

- Provided literature research and summary regarding drug stability for a medical device company.

H3-Biomedicine, Cambridge, MA (6/2017–10/2019) — *Pharmaceutical Development Consultant*

- Coordinated the radiolabeled synthesis of palbociclib, abemaciclib, and proprietary derivatives thereof; directed the stability studies and formulation process used in pharmacokinetic studies.
- Assisted with CMC in support of clinical trial material.

Missouri Board of Pharmacy (5/2019)

- Provided a consulting webinar regarding drug product degradation during mail-order pharmacy shipments and current 21 CFR, USP, and FDA industry guidance documents related to the subject.

EXPERT WITNESS EXPERIENCE

Ongoing Litigation

U.S.A. et al., ex rel. Stan Ellis v. CVS Health Corporation, et al. (2/2025–Present)

Case No. 2:16-cv-01582-GAM | Counsel: Motley Rice | Client: U.S.A. et al., ex rel. Stan Ellis

- Drug product degradation during shipment.
- Reply report; deposition.

Amyndas Pharmaceuticals Single Member P.C. et al. v. Alexion Pharmaceuticals, Inc. et al. (3/2023–Present)

Civil Action No. 1:20-cv-12254-LTS-JCB | Counsel: Foley and Hoag | Client: Alexion Pharmaceuticals

- Trade secret case related to a biologic drug.
- Rebuttal report; deposition.

Mayor and City Council of Baltimore v. GlaxoSmithKline LLC, et al. (9/2023–Present)

Case No. C-24-C-20-004788 | Counsel: Grant & Eisenhofer P.A. | Client: Special Counsel to the Mayor of Baltimore

- Product liability related to Zantac.
- Opening report; deposition; rebuttal report; deposition.

Completed Matters

In the Matter of Certain Selective Thyroid Hormone Receptor-Beta Agonists, Processes for Manufacturing or Relating to Same, and Products Containing Same (2/2023–11/2023)

Investigation No. 337-TA-1352, United States International Trade Commission | Counsel: Kirkland & Ellis | Client: Ascletis Pharma Inc.

- ITC case involving trade secrets.
- Opening and rebuttal reports; two-day deposition; four hours of testimony at trial.

Novugen Oncology Sdn. Bhd. v. Novartis AG (8/2022–8/2023)

Suite No. WA-22IP-36-06/2021, High Court of Malaya at Kuala Lumpur (Commercial Division) | Counsel: Baker and McKenzie International (Wong & Partners Malaysia) | Client: Novartis

- Patent case; client is the patent holder.
- Opening and rebuttal reports; assisted counsel in cross-examination of opposing expert; 12 hours of testimony at trial.
- Court decision in favor of client.

The City of Trenton, MI v. Cassie Delon (8/2023)

- Pro bono matter. Provided an affidavit explaining the urine pharmacokinetics of benzoylecgonine (a cocaine metabolite) in heavy versus light cocaine use.
- Favorable outcome for the client.

State of Hawaii — In the Matter of Frederick L. Aldama (9/2023)

Case No. 23-02040

- Provided a declaration explaining the urine pharmacokinetics of dextromethorphan and the plausibility of normal OTC use.
- Favorable outcome for the client.

Zurvita (7/2022–4/2023)

DC-21-14606 | Counsel: Cook Keith & Davis

- Trade secret case. Testimony at hearing; cross-examined. Daubert challenge to testimony was rejected.

Codexis, Inc. v. Codex DNA, Inc. (7/2021–4/2022)

Case No. 3:20-CV-03503-MMC | Counsel: DLA Piper | Client: Codex DNA

- Trademark infringement case in the synthetic biology landscape.

- Opening and rebuttal reports; deposition; advised counsel in the deposition of opposing expert; pre-trial preparation prior to settlement.

Norton Rose Fulbright (5/2021–6/2021)

Case 168684

- Provided research and expert opinions regarding purported false-positive results from the Soberlink breathalyzer device.
- Favorable outcome for the client.

Sandoz Inc. et al. v. Cambridge Therapeutics Technologies LLC (10/2018–4/2019)

MER-L-002363-17 | Counsel: Greenberg Traurig | Client: Sandoz

- Contract dispute. Opening report.
- Corroborated pharmaceutical manufacturing, stability studies, and storage/shipping documents with 21 CFR to demonstrate compliance.

Silvergate Pharmaceuticals Inc. v. Bionpharma Inc. (6/2018–10/2018)

1:16-cv-00876 | Counsel: Taft Stettinius & Hollister LLP | Client: Bionpharma

- ANDA case.
- Provided a declaration regarding how a person skilled in the art would define a stability agent.

Thorne Research et al. v. Atlantic Pro-Nutrients (3/2016–5/2018)

2:13-cv-00784 | Counsel: Parsons Behle and Latimer | Client: Thorne Research

- Patent infringement case.
- Seven-hour deposition; testimony and cross-examination in Federal Court (jury trial).
- Advised counsel on two depositions; coordinated expert search; oversaw chemical analysis of the defendant's contested formulation.

Pfizer Inc. et al. v. Mylan Inc. et al. (4/2016–12/2016)

1:15-cv-00026 | Counsel: Parker Poe | Client: Mylan Pharmaceuticals

- Hatch-Waxman ANDA patent infringement litigation.
- Prepared expert reports regarding the invalidity of plaintiff's patents concerning the reformulation of a drug product, including obviousness analysis based on prior art.
- Prepared reply reports addressing opposing experts' responsive reports.
- Seven-hour deposition; pre-trial preparation prior to settlement.

TEACHING EXPERIENCE

Roger Williams University, Bristol, RI (9/2020–Present) — *Adjunct Professor*

- Chemistry Laboratory classes.

Salve Regina University, Newport, RI (9/2014–5/2022) — *Adjunct Professor*

- Organic Chemistry, Forensic Science, and Earth Science lecture classes.

SKILLS AND TECHNIQUES

- **Expert Witness Consulting**: Report writing, deposition experience, trial testimony, and pre-trial preparation.
- **Medicinal Chemistry**: Discovered multiple clinical candidates (see Paratek Pharmaceuticals experience).
- **Drug Formulation**: Developed stable formulations for hundreds of drugs for preclinical testing.
- **Synthetic Organic Chemistry**: Extensive work with tetracycline natural products, pioneering mild reaction conditions suitable for this class of compounds. Cross couplings, transition metal catalysis, formylation, iodination, and peptide coupling reactions.
- **Analytical**: TLC, IR, 1H NMR, 13C NMR, 2D NMR, HPLC, and LC-MS.

- **Purification**: Analytical and preparative HPLC and flash chromatography.

PATENTS

1. Paul Abato and Todd Bowser. **7-Disubstituted-Ph tetracycline compounds for the Treatment of SMA.** PCT Int. Appl. (2013), WO 2013181391.

2. Abato, Paul; Bowser, Todd; Higgins, Paul; Verma, Atul; Zhang-Hoover, Jie. **Tetracycline Compounds for the Treatment of Rheumatoid Arthritis and Related Methods of Treatment.** PCT Int. Appl. (2010), WO 2010033939 A1.

3. Abato, Paul; Assefa, Haregewein; Berniac, Joel; Bhatia, Beena; Bowser, Todd; Grier, Mark; Honeyman, Laura; Ismail, Mohamed; Kim, Oak K.; Nelson, Mark; Pan, Jingwen; Verma, Atul. **Substituted tetracycline compounds for treatment of bacterial infections and neoplasms.** PCT Int. Appl. (2008), WO 2008079339 A2.

4. Abato, Paul; Assefa, Haregewein; Berniac, Joel; Bowser, Todd; Chen, Jackson; Grier, Mark; Honeyman, Laura. **Preparation of 10-substituted tetracycline compounds as antibiotics.** PCT Int. Appl. (2007), WO 2007014154 A2.

5. Abato, Paul; Assefa, Haregewein; Berniac, Joel; Bhatia, Beena; Bowser, Todd; Chen, Jackson; Grier, Mark; Honeyman, Laura; Ismail, Mohamed Y.; Nelson, Mark; Kwasi, Ohemeng; Pan, Jingwen. **Preparation of substituted tetracycline compounds for the treatment of bacterial infections and neoplasms.** PCT Int. Appl. (2006), WO 2006047756 A2.

6. Nelson, Mark L.; Ohemeng, Kwasi; Amoo, Victor; Kim, Oak; Abato, Paul; et al. **Preparation of substituted tetracycline analogs for use in antibiotic pharmaceutical compositions.** PCT Int. Appl. (2005), WO 2005009943 A2.

7. Nelson, Mark L.; Ohemeng, Kwasi; Frechette, Roger; Abato, Paul; et al. **Preparation of substituted tetracycline compounds for the treatment of bacterial infections and neoplasms.** PCT Int. Appl. (2003), WO 2003079984 A2.

PUBLICATIONS

1. "PTK-SMA2, **A novel splice-correcting tetracycline derivative, increases SMN protein expression and significantly improves survival in Type I SMA mice.**" Paul Abato, Francine Jodelka, Paul Higgins, Jie-Zhang Hoover, Kevin Klausner, Caroline Dudley, Juan Du, Sujatha Kumar, Michelle Hastings, and Todd Bowser. Poster, 2012 Annual Families of SMA Meeting, Bloomington, MN, June 21–23, 2012.

2. Hastings ML, Berniac J, Liu YH, Abato P, Jodelka FM, et al. **Tetracyclines that promote SMN2 exon 7 splicing as therapeutics for spinal muscular atrophy.** *Sci. Transl. Med.* (2009) Nov 4;1(5).

3. Nelson, Mark L.; Honeyman, Laura; Ismail, Mohamed; et al.; Abato, Paul; Assefa, Haregewein. **Synthesis of diverse tetracycline derivatives via Pd-catalyzed reactions: Creation of a large collection of novel 3rd generation tetracyclines.** 231st ACS National Meeting, Atlanta, GA, March 26–30, 2006.

4. Paul Abato, Courtney M. Yuen, Jeanne Y. Cubanski, and Christopher T. Seto. **Inhibitors of Plasmin that Extend into Both the S and S' Binding Sites: Cooperative Interactions Between S1 and S2.** *J. Org. Chem.* 2002, 67(4), 1184–1191.

5. Paul Abato and Christopher T. Seto. **EMDee: An Enzymatic Method for Determining Enantiomeric Excess.** *J. Am. Chem. Soc.* 2001, 123, 9206–9207.

6. Paul Abato, Jeffrey L. Conroy, and Christopher T. Seto. **Combinatorial Library of Serine and Cysteine Protease Inhibitors that Interact with Both the S and S' Binding Sites.** *J. Med. Chem.* 1999, 42, 4001–4009.

7. Jeffrey L. Conroy, Paul Abato, Mousumi Ghosh, Mariana I. Austermuhle, Michel R. Kiefer, and Christopher T. Seto. **Synthesis of Cyclohexanone-Based Cathepsin B Inhibitors that Interact with Both the S and S' Binding Sites.** *Tetrahedron Lett.* 1998, 39, 8253–8255.