

DAVID RICHARD DODDS

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SUMMARY

Over fifteen years of successful interdisciplinary consulting at the interface of organic chemistry, molecular biology and fermentation, plus 15 years industrial experience. CTO-level service to small/start-up pharma and industrial biotech/renewables companies including technical direction of scientists, patent liaison, and IP strategy. Technical due diligence for investment and funding decisions, and expert witness service for patent infringement litigation. Extensive interdisciplinary, hands-on management experience covering organic chemistry, molecular biology, biotransformations & biocatalysis, microbial strain development (recombinant & classical), fermentation and process development & scale-up in multiple projects, including projects which required integrating all of these disciplines into a single process. Delivered profit-making IP covering chemo-enzymatic processes. Developed and scaled combined biological/chemical processes for the production of commodity chemicals from biomass. Directed multi-disciplinary process development groups in both major pharmaceutical corporations and small start-ups, and built new, practical technology bases in these environments. Extensive experience under GMP for API production via fully synthetic processes, semi-synthetic, and natural product fermentations. Provide CMC sections of IND & NDA filings plus response to FDA. Service as Chairs of international symposia in the field of biocatalysis, and as speaker & moderator at numerous conferences on bio-based chemicals.

APPOINTMENTS

- 2002 - President, Dodds & Associates LLC
- 2016 - Member, Lee Enterprises Renewable Chemicals Team
- 2014 - Executive officer, ASTM Committee E62 Industrial Biotechnology
- 2012 - Co-founder, Sriya DXI LLC
- 2012 - PureVison Technology, Inc. Scientific Advisory Board
- 2005 - Sr. Advisor, Rondaxe Pharma LLC
- 2002 - zuChem Scientific Advisory Board & CSO zuSyn Inc., (2006-2008)
- 2012-15 CTO, Pronghorn Renewables LLC
- 2009-12 Kent BioEnergy Scientific Advisory Board
- 2009-11 Sr. Advisor, Draths Inc. (acquired by Amyris)
- 2003-06 Sr. Advisor, Michigan Biotechnology Institute (MBI)
- 2002-08 Codexis Industrial Advisory Board
- 1999-01 Director, Fermentation & Biocatalysis Development, Bristol-Myers Squibb
- 1991-99 Manager, Biotransformations Group, Schering-Plough Research Institute
- 1986-91 Sr. Protein Biochemist, Sepracor Inc.

PRESENTATIONS, PATENTS and PUBLICATIONS

Attached.

EDUCATION

- 1984-86 MRC of Canada Post-doctoral Fellow in Molecular Biology, University of Colorado, Boulder; Prof. Marvin H. Caruthers
- 1979-84 Ph.D. Organic Synthesis, University of Toronto; Prof. J. Bryan Jones
- 1977-79 M.Sc. Biological Chemistry, University of Toronto
- 1973-77 B.Sc. Biochemistry, Trinity College, University of Toronto

PROFESSIONAL EXPERIENCE

INDEPENDENT CONSULTING; DODDS & ASSOCIATES LLC

2002 -

Founded Dodds & Associates to provide strategic technical planning and hands-on project management to the pharmaceutical, industrial biotech, and biobased/green chemical industries. Provide CTO-level service to small and start-up companies at interface of chemistry, molecular biology and fermentation. Provide day-to-day and strategic direction of scientific staff in these disciplines, including academic contacts. Executed contracts with over 30 clients since 2002; two projects ended with licensing of the project by large pharma houses, and a non-pharma client was acquired for their IP. Organized, moderated and chaired multiple conference panels and sessions seating senior industry executives.

Completed and current projects include:

- Senior technical executive for small entities:
 - interim CTO service; management of science program, responsible for lab build-out, expansion of technology base, contract work & staffing
 - technical direction of chemists, biologists and engineers, from broadly strategic to highly detailed
 - identification and presentation of technical opportunities to the fund, ranging from white-papers for specific technical areas to identifying contract sites and equipment for virtual companies
 - IP strategy and competitive analysis, patent liaison
 - significant experience with academic founders, university licensing groups, and senior management in an interdisciplinary start-up environment; presentations to regional development committees
- Project Management; organic chemistry, molecular biology, fermentation and microbiology:
 - development and scale-up of both fermentation and chemical processes for pharma and biobased chemicals projects including strain development, molecular biology, organic synthesis and chemical route selection, biocatalysis and downstream processing
 - provide RFPs for bidding both fermentations and total chemical syntheses, plus CMO selection
 - draft batch records and process validations, CMC sections for IND & NDA filings
 - single point of contact for clients' outsourced projects after project awarded to contractors; direct technical support of CMO for client including on-site meetings at foreign locations
 - single point of contact with academic faculty advising or performing services for clients
 - technical transfer of processes and analytical methods, including documentation
 - management and technical support for total syntheses, fermentations and strain development
- Technical due diligence for multiple clients in both bio-based chemicals and pharmaceutical industries
- Service on Scientific Advisory Boards; technical presentations to Corporate Board and investors
- Co-founder of Pronghorn Renewables and SriyaDXI
- Expert witness service primarily for litigation for patent infringement, or contract disputes concerning chemical and biological operations and processes
 - experience in opinions, depositions, affidavits, and cross-examinations; court experience

BRISTOL-MYERS SQUIBB Co., SYRACUSE, NEW YORK

DIRECTOR, FERMENTATION & BIOCATALYSIS DEVELOPMENT

1999 - 2001

Invited to BMS to lead a new group of 50 scientists organized into chemical process development, molecular biology, fermentation development, and GMP analytical functions. Achieved cost-savings by applying biocatalysis in chemical syntheses. Developed chiral chemical processes, plus fermentations for natural products, enzymes, and biocatalysis.

- Solved production problems with enzymatic process experienced by an external supplier. Recovered over 3 tons of in-process material critical to launch supply.
- Developed process to chiral intermediate for HIV therapeutic via recombinant enzyme system, allowing significant cost-savings over vendor pricing of tonne quantities.
- Developed natural product fermentation process that gave a three-fold increase in production.
- Conceived and managed chemical gene synthesis and expression project to replace bovine enzyme and eliminate TSE/BSE regulatory issues in an existing commercial process.
- Group submitted six chemical and fermentation process patent applications in 18 months.
- Responsible for multi-million dollar TAXOL[®] project with external partner. Reviewed all outside TAXOL[®] production technology and wrote technical reports as part of formal corporate response.
- Supported filing for commercial antibiotic synthesis using biocatalysis. Advised patent counsel on cross-licensing of production technology, avoiding patent conflicts and preserving future rights.

SCHERING-PLOUGH RESEARCH INSTITUTE, UNION, NEW JERSEY**1991 - 1999**

MANAGER, BIOTRANSFORMATIONS GROUP

Invited to SPRI to establish a new group for the development of biocatalysis for more efficient and cost-effective syntheses of pharmaceuticals. Reported to VPs of both Chemical and Biotechnology Development. Responsible for budget (operational, capital, grant), staffing and equipping, physical plant requirements, and all regulatory compliance (environmental, S&IH, GMP) for the Group.

- Successfully introduced biocatalysis under both aqueous and non-aqueous conditions in over a dozen projects, (including the approved POSACONAZOLE[®] antifungal) and handled all downstream processing required for product isolation and purification. Projects scales ranged from lab-scale synthesis of metabolites, to GMP plant processes providing 100s of kgs of intermediates for clinical material.
- Successfully doubled the capacity of a fermentation used to perform a chemical reaction in an existing manufacturing process, including downstream extraction and recovery.
- Directed group in filing of 13 patent disclosures. Six were issued as patents, and one was kept a trade secret. Group had a total of 37 public releases – extremely unusual for a development group.
- Independently proposed and initiated automation of enzyme screening activities, resulting in the approval of a \$1.25MM project. The project was completed and the equipment used for several years.

SEPRACOR INC., MARLBOROUGH, MASSACHUSETTS**1986 - 1991**

SENIOR PROTEIN BIOCHEMIST

Responsible for biocatalysis research to create commercial opportunities for Sepracor's core membrane bioreactor technology. Included design and chemical synthesis of substrates, design and implementation of enzyme/substrate screening assays, and technical support for engineering.

- Discovered unique class of ester substrates unusually susceptible to hydrolysis by proteolytic enzymes. Technology was successfully applied to the resolution of clinical quantities of NSAIDs.
- Established enzymology for multi-million dollar joint venture with Japanese pharmaceutical company for resolution of cardiac drug (DILTIAZEM[®]) intermediate, including enzymatic transformation of waste by-product to a commercially valuable fine chemical.
- Wrote patent applications for enzyme processes, and assisted in their prosecution. Chief technical witness in patent interference suit in which Sepracor prevailed.

CONFERENCE CHAIRS

- Invited session chair and panel moderator for multiple conferences covering bio-based chemicals
- InfoCast Summit, *Sustainable Chemicals & Plastics Adoption & Applications*; San Diego, CA, September 2015
- Informa Life Sciences Symposium, *The Commercialization and Application of Enzymes in Biotechnology*; Pre-conference Workshop on Biocatalysis, London, UK, March 2014
- BIO 2004 International Convention, *Biotechnology for Small Molecule Pharmaceutical Manufacturing*, San Francisco, June 2004
- 82ND Conference of the Chemical Society of Canada, “*Biocatalysis in the Service of Organic Chemistry: A Symposium in Honour of Professor J. Bryan Jones*”, Toronto, June 1999
- Gordon Research Conference, *Biocatalysis*, Kimball Union Academy, Meriden, NH, July 1998
- 5TH North American Chemistry Congress, Symposium on *Chemical Syntheses Using Biotransformations*, Cancun, Mexico, November 1997

INVITED TALKS

- *The Challenges of Reality*, 14th International Symposium on Bioplastics, Biocomposites and Biorefining, Guelph, Ontario, Canada, June 2, 2016
- *Bio-based Chemicals*
BCN Green Chemistry Workshop, Edmonton, Alberta, Canada, May 8, 2015
- *Problems & Opportunities*
Presentation to South Western Economic Alliance (Michigan/Ontario), Sarnia, ON, June 11, 2014
- *Carbon, Hydrogen and Biocatalysis*
Advanced Biofuels Leadership Conference, Washington, D.C. April 2014
- *Industrial Biocatalysis*
Pennsylvania State University, State College, PA, March 2013
- *Metabolic Routes to Aromatic Compounds*
Metabolic Design 2011, San Diego, CA, May 2011
- *Dry Pipelines; The Future of the Pharmaceutical Industry*
ACS New York Chapter, Chemical Marketing & Economics Group, New York City, June 2003
- *Biocatalysis in Development: Playing in the Viola Section*
CSIRO Workshop on Biocatalysis, Canberra, Australia, November 2002
- *Biocatalysis in Pharmaceutical Development*
BIO 2002 Conference, Toronto, Canada, June 2002
- *Biocatalysis in the Pharmaceutical Industry*
Center for Biocatalysis and Bioprocessing, Iowa City, IA, October 1999
- *Biocatalysis in the Pharmaceutical Industry: Practical Challenges and Experience*
Society for Industrial Microbiology Annual Meeting, Denver, Colorado, August 1998
- *Industrial Biocatalysis; Current Trends and Future Opportunities*
New Frontiers in Screening for Microbial Biocatalysts, Ede, Netherlands, December 1996
- *Screening and Use of Enzymes for Synthetic Applications in the Pharmaceutical Industry*
Chiral Europe 95, London, U.K., September 1995
- *Applications of Biocatalysis in the Pharmaceutical Industry*
BRIDGE Final Sectorial Meeting on Biotransformations, Wageningen, Netherlands, October 1994
- *Novel Water-soluble Esters as Substrates for Enantiomeric Resolution by Proteases*
Biocatalysis for the 90's, Lake Buena Vista, Florida, June 1991

ISSUED PATENTS & PUBLISHED (*unpublished*) APPLICATIONS

- US 62/357,149 "Digital Experience Satisfaction Index; Method Of Determining And Uses Of Such Index", Dodds, David R., Kilambi, Srinivas, Mukkavilli, Mahadevan, Suresh; filed 30 JUN 2016
- US 62/308,175 "Improved Method for Using Electrochemical Bioreactor Module with Recovery of Cofactor", Morrison, Clifford S., Armiger, William B., Dodds, David R.; filed 14 MAR 2016
- WO2016141247A1 "Methods And Systems For Post-Fermentation Lignin Recovery", Armiger, William B., Dodds, David R.; 09 SEP 2016
- WO2016137976A1 "Electrochemical Bioreactor Module and Engineered Metabolic Pathways for 1-Butanol Production with High Carbon Efficiency", Dodds, David R., Armiger, William B., Koffas, Mattheos; 01 SEP 2016
- WO2016070168A1 "Improved Electrochemical Bioreactor Module and Use Thereof", Armiger, William B., Dodds, David R.; 06 MAY 2016
- WO2014152366A1 "Production of Alcohols, Diols, Cyclic Ethers and Lactones from Pentose and Hexose Sugars", David Dodds, Srinivas Kilambi, Gregory Luli; 25 SEP 2014
- WO2014039767A1 "Electrochemical Bioreactor Module and Methods of Using the Same", Armiger, Travis J., Armiger, William B., Dodds, David R.; 13 MAR 2014
- US 6 521 455 B1 "Process For Preparing Optically Active Glycidate Esters", Dodds, David R.; Lopez, Jorge L.; Zepp, Charles M.; Brandt, Steven; Feb. 18, 2003
- US 5 274 300 "Enzymatic Hydrolysis of Glycidate Esters in the Presence of Bisulfite Anion", Dodds, David R.; Lopez, Jorge L.; Dec. 28, 1993
- US 5 198 568 "Compounds Useful In Enzymatic Resolution Systems And Their Preparation", Zepp, Charles M.; Wald, Stephen A.; Dodds, David R.; Mar. 30, 1993
- US 5 196 568 "Compounds Useful In Enzymatic Resolution Systems And Their Preparation", Zepp, Charles M.; Wald, Stephen A.; Dodds, David R.; Mar. 23, 1993
- US 5 167 824 "Separation By Carrier Mediated Transport", Cohen, Charles; Dishman, Robert A.; Huston, James S.; Bratzler, Robert L.; Dodds, David R.; Zepp, Charles M.; Dec. 1, 1992
- US 5 077 217 "Method For Membrane Reactor Resolution Of Stereoisomers", Matson, Stephen L.; Wald, Stephen A.; Zepp, Charles M.; Dodds, David R.; Dec. 31, 1991
- US 5 057 427 "Method For Resolution Of Stereoisomers", Wald, Stephen A.; Matson, Stephen L.; Zepp, Charles M.; Dodds, David R.; Oct. 15, 1991
- EP 0 657 544 B1 "Process For Preparing Optically Active Glycidate Esters", Dodds, David R.; Lopez, Jorge L.; Zepp, Charles M.; Brandt, Steven; Rossi, Richard F.; 21.12.1997
- EP 0 461 043 A2 "Enantiomer Separation By Transesterification", Dodds, David R.; Zepp, Charles M.; Rossi, Richard F.; 11.12.91
- EP 0 440 723 B1 "Process For Preparing Optically Active Glycidate Esters", Dodds, David R.; Lopez, Jorge L.; Zepp, Charles M.; Brandt, Steven; 16.08.95
- EP 0 423 133 B1 "Enzymatic Resolution Systems And Compounds Useful In The Systems And Their Preparations", Matson, Stephen, L.; Wald, Stephen, A.; Zepp, Charles, M.; Dodds, David, R.; 20.09.95

REVIEWED PUBLICATIONS

- David R. Dodds, "Antibiotic Resistance; A Current Epilogue", *Biochemical Pharmacology*, accepted. Available online, <http://dx.doi.org/10.1016/j.bcp.2016.12.005>
- David Dodds, Bob Humphreys, "Production of Aromatic Chemicals from Biobased Feedstock", Chapter 8 (pp.183-237) in *Catalytic Process Development for Renewable Materials*, Pieter Imhof, Jan Cornelis van der Waal Eds., Wiley-VCH, 2013
- David R. Dodds, Richard A. Gross, "Chemicals From Biomass", *Science*, **318**, 1250-51, (2007)
- Michael J. Homann, Robert B. Vail, Edward Previte, Maria Tamarez, Brian Morgan, David R. Dodds, Aleksey Zaks, "Rapid Identification of Enantioselective Ketone Reductions Using Targeted Microbial Libraries", *Tetrahedron*, **60**, 789-797, (2004) Awarded "Most Referenced Paper", 2004-2007
- Michael J. Homann, Robert Vail, Brian Morgan, Vijay Sabesan, Cliff Levy, David R. Dodds, Aleksey Zaks, "Enzymatic Hydrolysis of a Prochiral 3-Substituted Glutarate Ester, An Intermediate in the Synthesis of NK1/NK2 Dual Antagonist", *Adv. Synth. & Catalysis*, **343**(6-7), 744-749, (2001)
- Morgan, Brian; Dodds, David R.; Homann, Michael J.; Zaks, Aleksey; Vail, Robert; "Biocatalysis in Pharmaceutical Process Development: SCH56592, A Case Study", *Methods in Biotechnology*, **15**(Enzymes in Nonaqueous Solvents): 423-467, (2001)
- Brian Morgan, Aleksey Zaks, David R. Dodds, Jinchu Liu, Rama Jain, Sreeni Megati, F. George Njoroge, Viyyoor M. Girijavallabhan, "Enzymatic Kinetic Resolution of Piperidine Atropisomers: Synthesis of a Key Intermediate of the Farnesyl Protein Transferase Inhibitor, SCH66336", *J. Org. Chem.*, **65**(18), 5451-5459 (2000)
- Brian Morgan, Bashkar R. Sarikonda, David R. Dodds, Michael J. Homann, Robert Vail, "Enzymatic Synthesis of Enantio- and Diastereomerically Enriched *syn*-3-Nitro-2-pentanol", *Tetrahedron: Asymmetry*, **10**(1999), 3681-3690
- Aleksey Zaks, David R. Dodds, "Biotransformations in the Discovery and Development of Pharmaceuticals", *Current Opinions in Drug Discovery & Development*, **1**(3), 290-303 (1998)
- Aleksey Zaks, David R. Dodds, "Enzymatic Glucuronidation of a Novel Cholesterol Absorption Inhibitor, SCH 58235", *Appl. Biochem. Biotech.*, **73**, 205-214 (1998)
- Brian Morgan, Brent R. Stockwell, David R. Dodds, David R. Andrews, Anantha R. Sudhakar, Christopher M. Neilsen, Ingrid Mergelsberg, Arne Zumach, "Chemoenzymatic Approaches to SCH 56592, A New Azole Antifungal", *J. Amer. Oil Chem. Soc.*, **74**(11), 1361-1370 (1997)
- David R. Dodds, Aleksey Zaks, "Application of Biocatalysis and Biotransformations to the Synthesis of Pharmaceuticals", *Drug Discov. Today*, **2**(12), 513-531 (1997)
- Brian Morgan, David R. Dodds, Aleksey Zaks, David R. Andrews, Ricardo Klesse, "Enzymatic Desymmetrization of Prochiral 2-Substituted-1,3-propanediols: A Practical Chemoenzymatic Synthesis of a Key Precursor of SCH 51048, a Broad-Spectrum Orally Active Antifungal Agent", *J. Org. Chem.*, **62**(22), 7736-7743 (1997)
- D.R. Dodds, C. Heinzelman, M. Homann, W.B. Morgan, E. Previte, R.A. Roehl, R. Vail, A. Zaks, "Biocatalysis at The Schering-Plough Research Institute", *Chimica Oggi* **14**, 9 (1996)
- Aleksey Zaks, Asha V. Yabannavar, David R. Dodds, C. Anderson Evans, Pradip R. Das, Rodney Malchow, "A Novel Application of Chloroperoxidase: Preparation of *gem*-Halonoitro Compounds", *J. Org. Chem.*, **61**(24), 8692-695 (1996)
- Aleksey Zaks, David R. Dodds, "Chloroperoxidase-Catalyzed Asymmetric Oxidations: Substrate Specificity and Mechanistic Study", *J. Am. Chem. Soc.*, **117**(42), 10419-10424 (1995)

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Dodds, D.R., Andrews, D.R., Heinzelman, C., Homann, M.J., Klesse, P., Morgan, W.B., Previte, E., Sudhakar, A., Roehl, R.A., Vail, R., Zaks, A., Zelazowski, A., *Proceedings of Chiral Europe '95 (London)*, pp. 55-62 (1995)

Brian Morgan, Greg Bydlinski, David R. Dodds, "A Chemoenzymatic Synthesis of Both Enantiomers of 2-Phenyl-3-hydroxypropylcarbamate, a Metabolite of Felbamate", *Tetrahedron: Asymmetry*, **6**(7), 1765-1772 (1995)

D.R. Dodds, E. Toone, Eds., "Biological Catalysis: Models, Methods and Applications - Parts I & II", Symposia-in-Print No.1, *Bioorganic and Medicinal Chemistry*, **2**, issues 6&7 (1994)

David R. Dodds, J. Bryan Jones, "Enzymes in Organic Synthesis 38. Preparations of Enantiomerically Pure Chiral Hydroxydecalinones via Stereospecific Horse Liver Alcohol Dehydrogenase Catalyzed Reductions of Decalindiones", *J. Am. Chem. Soc.*, **110**(2), 577-583 (1988)

J. Bryan Jones, David R. Dodds, "Enzymes in Organic Synthesis 37. Preparation and Characterization of Potential Substrates of Horse Liver Alcohol Dehydrogenase", *Can. J. Chem.*, **65**(10), 2397-2404 (1987)

Caruthers, M.H., Barone, A.D., Beaucage, S., Dodds, D.R., Fisher, E. McBride, L.F., Matteucci, M., Stabinsky, I., Tang, J-Y., "Chemical Synthesis of Deoxyoligonucleotides by the Phosphoramidite Method", *Meth. Enzymol.*, **154** (Recomb. DNA Pt. E), 287-313 (1987)

Caruthers, M.H., Barone, A.D., Beltman, J., Bracco, L.P., Dodds, D.R., Dubendorf, J.M., Eisenbeis, S.J., Gayle, R.B., Prosser, K., Rosendahl, M.S., Sutton, J., Tang, J-Y., "The Interaction of Cro, cl, and RNA Polymerase with Operators and Promoters", *UCLA Symp. Mol. Cell. Biol.*, **1**(Prot. Struct. Fold. Des.), 221-228 (1986)

Eisenbeis, S.J., Nasoff, M.S., Noble, S.A., Bracco, L.P., Dodds, D.R., Caruthers, M.H., "Altered Cro Repressors From Engineered Mutagenesis of a Synthetic *cro* Gene", *Proc. Natl. Acad. Sci. USA*, **82**(4), 1084-1088 (1985)

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David R. Dodds, J. Bryan Jones, "Selective And Stereospecific Enzyme Catalysed Reductions of cis- and trans-Decalindiones to Enantiomerically Pure Hydroxyketones; An Efficient Synthesis of (+)-4-Twistanone", *J. Chem. Soc. Chem. Comm.*, **1982**(18), 1080-1081

David R. Dodds, J. Bryan Jones, "Enzymes in Organic Synthesis 17. Oxido-reductions of Alcohols, Aldehydes, and Ketones Using Chemically Modified Horse Liver Alcohol Dehydrogenase", *Can. J. Chem.*, **57**(19), 2533-2538 (1977)