

Leonard J. Chyall, Ph.D.

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Education

B.A. (Chemistry), 1986, Oberlin College, Oberlin, OH
Ph.D. (Chemistry), 1991, University of Minnesota, Minneapolis, MN
Postdoctoral Fellow, 1992-1996, Purdue University, West Lafayette, IN
Pharmaceutical Solids and Regulatory Affairs Short Course, Purdue University, 2001

Employment

- May 2011 – Chyall Pharmaceutical Consulting, LLC; West Lafayette, Indiana
President and Consultant**
Independent consultant serving the pharmaceutical industry. Expertise in synthetic chemistry, and analytical testing of drug substances and drug products. Services directed toward scientific data and document review, laboratory testing, and technical assistance with IP matters.
- 2000-2011 Aptuit, Inc. (formerly SSCI, Inc.), West Lafayette, Indiana**
Director (August 2010 – May 2011)
Principal (January 2007 – July 2010)
Senior Research Investigator (2003 - 2006)
Research Investigator (2000 - 2003)
Project manager and group leader for external client projects involving various aspects of organic and analytical chemistry. These projects involve the development of new products (primarily pharmaceuticals) or providing scientific consulting to support patent litigation, counterfeit analysis or tampering analysis projects. Leader of a department responsible for fee-for-service laboratory testing and consulting services. Responsible for business development, client relations, and strategic planning of the business. Administrative supervisor for numerous chemists throughout my tenure with the organization.
- 1996-2000 Great Lakes Chemical (now Chemtura), West Lafayette, Indiana
Research Chemist**
Lead Scientist for a new technology development program in the GLCC Corporate R&D division. Technology Coordinator for contract research programs. Project Leader for a new product development project in GLCC Polymer Additives R&D.

Representative Technical Skills

Analytical Chemistry

- X-ray powder diffraction (XRPD)
- Thermogravimetric analyses (TGA)
- Differential scanning calorimetry (DSC)
- Optical microscopy
- Infrared (IR) and Raman spectroscopy
- Moisture sorption/desorption analyses
- NMR spectroscopy
- Spectrophotometry
- Solubility and dissolution testing
- pH measurements, potentiometric titrations
- Karl Fischer analyses

Organic Chemistry

- Synthetic chemistry
 - mg to kg scale laboratory reactions
 - high pressure reactions
 - air-sensitive procedures
- Crystallization methods
- Enantiomer Resolutions
- Polymorph, salt and cocrystal screening and characterization
- Analytical chromatography (HPLC and TLC)
- Preparative chromatography

Professional Affiliations

- American Chemical Society
- American Association of Pharmaceutical Scientists
- Purdue Research Park Life Sciences Executive Council

Publications

1. Chyall, L. J. Current Applications of X-Ray Powder Diffraction in the Pharmaceutical Industry *Am. Pharm. Rev.* **2012**, *15*, 70-73.
2. Park, A.; Chyall, L.; Dunlap, J.; Schertz, C.; Jonaitis, D.; Stahly, B.; Bates, S.; Shipplett, R.; Childs, S. New solid-state chemistry technologies to bring better drugs to market: knowledge-based decision making. *Exp. Opin. Drug Disc.*, **2007**, *2(1)*, 145-154.
3. Lohani, S.; Zhang, Y.; Chyall, L. J.; Mougin-Andres, P.; Muller, F. X.; Grant, D. J. W. Carbamazepine-2,2,2-trifluoroethanol (1/1). *Acta Cryst.* **2005**, *E61*, 1310-1312.
4. Childs, S. L.; Chyall, L. J.; Dunlap, J. T.; Smolenskaya, V. N.; Stahly, B. C.; Stahly, G. P. Crystal Engineering Approach to Forming Cocrystals of Amine Hydrochlorides with Organic Acids. Molecular Complexes of Fluoxetine Hydrochloride with Benzoic, Succinic, and Fumaric Acids. *J. Am. Chem. Soc.* **2004**, *126*, 13335-13342.
5. Childs, S. L.; Chyall, L. J.; Dunlap, J. T.; Coates, D. A.; Stahly, B. C.; Stahly, G. P. A Metastable Polymorph of Metformin Hydrochloride: Isolation and Characterization Using Capillary Crystallization and Thermal Microscopy Techniques. *Crystal Growth & Design* **2004**, *4*, 441-449.
6. Chyall, L. J.; Tower, J. M.; Coates, D. A.; Houston, T. L.; Childs, S. L. Polymorph Generation in Capillary Spaces: The Preparation and Structural Analysis of a Metastable Polymorph of Nabumetone. *Crystal Growth & Design* **2002**, *2*, 505-510.

7. Morgan, A. B.; Harris, R. H., Jr.; Kashiwagi, T.; Chyall, L. J.; Gilman, J. W. Flammability of polystyrene layered silicate (clay) nanocomposites: Carbonaceous char formation. *Fire and Materials* **2002**, *26*, 247-253.
8. Hill, B. T.; Poutsma, J. C.; Chyall, L. J.; Hu, J.; Squires, R. R. Distonic ions of the "Ate" class. *J. Am. Soc. Mass Spectrom.* **1999**, *10*(9), 896-906.
9. Gassman, P. G.; Han, S.; Chyall, L. J. Thermal rearrangement of trans-7,7-dihalobicyclo[4.1.0]hept-3-enes. *Tetrahedron Lett.* **1998**, *39*(31), 5459-5462.
10. Poutsma, J. C.; Seburg, R. A.; Chyall, L. J.; Sunderlin, L. S.; Hill, B. T.; Hu, J.; Squires, R. R. Combining Electrospray Ionization and the Flowing Afterglow Method. *Rapid Commun. Mass Spectrom.* **1997**, *11*, 489-493.
11. Chyall, L. J.; Squires, R. R. The Proton Affinity and Absolute Heat of Formation of Trifluoromethanol. *J. Phys. Chem.* **1996**, *100*, 16435-16440.
12. Leeck, D. T.; Li, R.; Chyall, L. J.; Kenttämaa, H. I. Homolytic Se-H Bond Energy and Ionization Energy of Benzeneselenol, and the Acidity of the Corresponding Radical Cation. *J. Phys. Chem.* **1996**, *100*, 6608-6611.
13. Chyall, L. J.; Squires, R. R. Determination of the proton affinity and absolute heat of formation of cyclopropenylidene. *Int. J. Mass Spectrom. Ion Processes* **1995**, *149/150*, 257-266.
14. Smith, R. L.; Chyall, L. J.; Beasley, B. J.; Kenttämaa, H. I. The Site of Protonation of Aniline. *J. Am. Chem. Soc.* **1995**, *117*, 7971-7973.
15. Chou, P. K.; Smith, R. L.; Chyall, L. J.; Kenttämaa, H. I. Reactivity of the Prototype Organosulfur Distonic Ion: $\cdot\text{CH}_2\text{SH}_2^+$ *J. Am. Chem. Soc.* **1995**, *117*, 4374-4378.
16. Chyall, L. J.; Kenttämaa, H. I. Gas-phase reactions of the 4-dehydroanilinium ion and its isomers. *J. Mass Spectrom.* **1995**, *30*, 81-87.
17. Chyall, L. J.; Byrd, M. H. C.; Kenttämaa, H. I. Reactions of the Charged Radical $(\text{CH}_3)_2\text{S}^+-\text{CH}_2\cdot$ with Cyclic Alkenes. *J. Am. Chem. Soc.* **1994**, *116*, 10767-10772.
18. Chyall, L. J.; Brickhouse, M. D.; Schnute, M. E.; Squires, R. R. Kinetic versus Thermodynamic Control in the Deprotonation of Unsymmetrical Ketones in the Gas Phase. *J. Am. Chem. Soc.* **1994**, *116*, 8681-8690.
19. Chyall, L. J.; Kenttämaa, H. I. The 4-Dehydroanilinium Ion: a Stable Distonic Isomer of Ionized Aniline. *J. Am. Chem. Soc.* **1994**, *116*, 3135-3136.
20. Smith, R. L.; Chyall, L. J.; Stirk, K. M.; Kenttämaa, H. I. Radical-type reactivity of the methylenedimethylsulfonium ion, $(\text{CH}_3)_2\text{S}^+-\text{CH}_2\cdot$ *Org. Mass Spectrom.* **1993**, *28*, 1623-1631.
21. Smith, R. L.; Chyall, L. J.; Chou, P. K.; Kenttämaa, H. I. The Acyclic Distonic Isomer of Ionized Cyclopentanone: $\cdot\text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_2\text{CO}^+$ *J. Am. Chem. Soc.* **1994**, *116*, 781-782.
22. Mlinaric-Majerski, K.; Vinkovic, V.; Chyall, L. J.; Gassman, P. G. Deuterium isotope effects on nuclear shielding. Cross-ring effects in rigid cyclic molecules. *Magn. Reson. Chem.* **1993**, *31*, 903-905.

23. Brickhouse, M. D.; Chyall, L. J.; Sunderlin, L. S.; Squires, R. R. Kinetics of isobaric ion/molecule reactions determined by the flowing afterglow-triple quadrupole technique. *Rapid Commun. Mass Spectrom.* **1993**, *7*, 383-3

Patents

1. Gushurst, K. S.; Chyall, L. J.; Koztecki, L. H.; Wolfe, B. S. Crystalline forms of oxymorphone hydrochloride US 8,563,571 (October 22, 2013).
2. Quigley, K. A.; Still, E. J.; Chyall, L. J. 4-[3[(4-Cyclopropanecarbonyl-piperazine-1-carbonyl-4-fluorobenzyl)-2H-phthalazin-1-one. US 8,183,369 B2 (May 22, 2012).
3. Chyall, L. J.; Hodgen, H. A.; Vyverberg, F. J.; Chapman, R. W. Intumescent Polymer Compositions. US 6,905,693 (June 14, 2005).
4. Chyall, L. J.; Hodgen, H. A.; Vyverberg, F. J.; Chapman, R. W.; Chou, P. K. Intumescent Polymer Compositions. US 6,632,442 B1 (October 14, 2003).
5. Robin, M. L.; Mazac, C. J.; Chyall, L. J.; Kleindl, P. Bromine-containing 1,2-bis(phenyl)difluoromethanes and method of imparting flame retardancy to flammable materials. US 6,348,633 (February 19, 2002).

Papers Presented

1. "Crystallization Studies of Nabumetone: Preparation and Characterization of a Novel, High-Energy Polymorph." Chyall, L. J.; Tower, J. M.; Coates, D. A.; Houston, T. L., 223rd National Meeting of the American Chemical Society, Orlando, FL, April 7-11, 2002: Abstract IEC 268
2. "The Synthesis and Properties of 7,7-Dichloro-*trans*-bicyclo-[4.1.0]-hept-3-ene." P. G. Gassman and L. J. Chyall, 22nd Great Lakes Regional Meeting of the American Chemical Society, Duluth, MN, May 31-June 2, 1989: Abstract 98.
3. "The Synthesis and Thermal Isomerization of 7,7-Dihalo-*trans*-bicyclo-[4.1.0]-hept-3-enes." P. G. Gassman and L. J. Chyall, 201st National Meeting of the American Chemical Society, Atlanta, GA, April 14-19, 1991: Abstract ORGN 228.
4. "Free Radical Rearrangements of Dihalo-*trans*-bicyclo-[4.1.0]-hept-3-enes." P. G. Gassman and L. J. Chyall, 32nd National Organic Chemistry Symposium, University of Minnesota, Minneapolis, MN, June 16-20, 1991: Abstract B-65.
5. "Kinetic Versus Equilibrium Control in the Deprotonation of Unsymmetrical Ketones in the Gas Phase." L. J. Chyall, M. D. Brickhouse, M. E. Schnute, and R. R. Squires, 205th National Meeting of the American Chemical Society, Denver, CO, March 28-April 2, 1993: Abstract ORGN 29.
6. "Ion-Molecule Chemistry of the Methylene Dimethylsulfonium Ion: A Novel Alpha-Distonic Ion." L. J. Chyall, R. L. Smith, K. M. Stirk, and H. I. Kenttämää, 41st ASMS Conference on Mass Spectrometry, San Francisco, CA, May 30-June 4, 1993: Abstract MOD 12:10

7. "Radical-Type Reactivity of Distonic Ions: The 4-Dehydroanilinium Ion." L. J. Chyall and H. I Kenttämä, 208th National Meeting of the American Chemical Society, Washington, DC, August 21-25, 1994: Abstract ORGN 404.
8. "Astrophysical Thermochemistry: The Heats of Formation of C₃H₂ Isomers." L. J. Chyall and R. R. Squires, 43rd ASMS Conference on Mass Spectrometry, Atlanta, GA, May 21-26, 1995: Abstract WOE 11:50.

Invited Lectures

1. "Environmentally Friendly Fire Suppression Technology." Department of Chemistry, Purdue University, West Lafayette, IN. April 8, 1997.
2. "The Proton Affinity and Absolute Heat of Formation of Trifluoromethanol." Joint Institute Laboratory for Astrophysics, University of Colorado, Boulder, CO. March 1, 1996.
3. "Understanding the Atmospheric Fate of Hydrofluorocarbons: Thermochemistry of Trifluoromethanol." Aeronomy Laboratory, National Oceanic and Atmospheric Administration, Boulder, CO. February 29, 1996.

Dissertation

Chyall, L. J. The synthesis and thermal rearrangements of 7,7-dibromo-*trans*-bicyclo[4.1.0]hept-3-ene and 7,7-dichloro-*trans*-bicyclo[4.1.0]hept-3-ene. (1991) 192 pp. Avail.: Univ. Microfilms Int., Order No. DA9209417 From: Diss. Abstr. Int. B 1992, 52(10), 5264.

Testimony at Deposition or at Trial (Previous 4 Years)

Testimony provided on behalf of underlined party.

1. Cephalon, Inc. v. Mylan Pharmaceuticals, Inc. *et al.* MDL Docket No. 1:10-md-2200-GMS (D.Del.) (deposition).
2. Shire LLC, et al. v. Amneal Pharmaceuticals LLC *et al.* C.A. No. 2:11-cv-03781-SRC-CLW (DNJ) (deposition).
3. Apotex, Inc. and Apotex Corp. v. UCB, Inc., Schwarz Pharma, Inc. and Kremers Urban Pharmaceuticals Inc. C.A. No. 0:12-cv-60706-DMM (S.D. Fla.) (deposition and trial).
4. Pfizer Inc., Wyeth Pharmaceuticals Inc. and PF Prism CV v. Apotex, Inc., *et al.* C.A. No. 12-808-SLR Consolidated (D. Del.) (deposition).
5. Opposition to Israel Patent Application No. IL172563, Teva Pharmaceutical Industries Ltd. v. Merck & Co. (hearing).
6. Pfizer Inc. and UCB Pharma GmbH v. Alkem Laboratories Ltd., *et al.* C.A. No. 13-1110 (GMS) Consolidated (D. Del.) (deposition and trial).

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