

Miscellaneous

Interview with Ed Chait, Ph.D. BASi Executive Vice President and Chief Scientific Officer



After distinguished service at both large and start-up firms, Dr. Chait returned to West Lafayette in the summer of 2005 to join BASi. He is managing the company's R/D and business development teams while considering M&A and technology licensing opportunities.

CSDD: Please review for our readers how you came around the circle back to West Lafayette where you completed your Ph.D. work in mass spectrometry at Purdue, working with Prof. Fred McLafferty.

Ed Chait: With nearly 40 years' experience in life sciences research, business development and marketing, and most recently as CEO of two venture-backed companies, I was looking for the ideal combination of corporate business and organizational challenge in an exciting intellectual environment. With its close ties to Purdue University and the West Lafayette community, BASi offered the entire package. It is great to be back to my educational roots, and I enjoy the emerging life sciences business community at the Purdue Research Park and in Indiana.

CSDD: What are your thoughts on the working environments in large and small technology firms and how has this changed over the last 35 years?

Ed Chait: When I started my career, it was enough just to do good science, and the world came flocking to your door. Now, life sciences is like any business – marketing is important, shareholders are looking for outstanding financial results, and customers demand quality and on-time performance. Good science is the foundation, but every day we learn how to do things faster and better. Each day the most important thing is that our clients are ever more satisfied with the services and products we deliver.

CSDD: Do you have any comments on what you've observed at BASi since you joined the company?

Ed Chait: BASi has achieved a lot in its 32-year history. Those accomplishments are based on the type of advanced science and innovation that built our world-class Bioanalytical services and our Culex systems. Going forward we have to use the talents of our employees more strategically to meet the ever-increasing demands of our clients in their quest to develop the next generation of pharmaceuticals. Our focus is shifting to the emerging biotechnology companies as clients. These organizations are leading the charge for new drugs. We are learning to contribute to this new culture of innovation and are altering our business development approach to have a dialog that will lead to business success for both our clients and for BASi.

CSDD: We imagine Indiana has changed quite a bit from the 1960s, beyond finally adopting daylight savings time this year. There are a number of state and university initiatives specifically related to life sciences. How do these look to you versus what you have seen in other states, recognizing that you recently spent time leading businesses in Connecticut, North Carolina and Texas?

Ed Chait: Indiana has changed a lot, becoming more prosperous, diverse and a nicer place to live. All of us know that the earth is small, and Indiana has a new world awareness of how its products and intellectual capital can be influential. Like all states, Indiana recognizes that life sciences offer fantastic dividends for the investment of intellectual capital from its universities and business community. The Indiana approach is aggressive, and certainly the state can be a contender in the race to develop new ideas and businesses. We need to use established businesses like BASi as a model and encourage young scientists and entrepreneurs to give birth to their ideas and nurture them in the State. All of us in business need to cultivate the interest of life sciences investors to make that possible.

CSDD: Finally, let's look at the personal side. You obviously enjoy what you do in business and science. What interests you on the avocational side?

Ed Chait: We are happy to be part of a university community for a variety of reasons. My neighbors are Purdue faculty members from every field, we can enjoy every kind of musical performance at Purdue as if we were still in the New York area, and we have world-class sports live at our doorstep. I am pursuing a life-long interest in serious scholarship in the history of science and technology, and one of these days I will probably get involved in restoring another sports car. With all this going on, my wife Carol and I also get opportunities to travel to interesting places. Hawaii is on our agenda for this summer.

Life Science Business Experiments in Indiana **Peter T. Kissinger, Ph.D., CEO**

Ten years ago, if anyone had asked what I might be doing now, there's one thing I surely never would have thought of – and that's leading a successful joint venture called Inproteo among IU, Purdue and Eli Lilly and Company.

Why? There are many reasons. For one thing, it was a rare occasion that our major institutions talked with each other about current research, never mind collaborated with each other.

I believe we're in a better position now than we were a decade ago, even a few years ago, to support business growth. Efforts such as BioCrossroads and the activity at Purdue's Discovery Park and IU's Emerging Technologies Center, for example, are making Indiana a haven for innovation – by supporting the strong research programs at our universities, encouraging commercialization of intellectual property and paving the way for new life sciences companies to succeed.

We've got a burgeoning small business cluster in the life

sciences with successful companies like BASi (of which I'm also CEO), Endocyte, SSCI, GAT and QuadraSpec (to name just a few at the Purdue Research Park). The commitment to build and support more small companies like these in Indiana is critical to our future.

Inproteo was built on the analytical chemistry strengths at IU and Purdue (which feature two of the top four analytical chemistry programs in the nation), combined with the pharmaceutical expertise found at Eli Lilly. Inproteo brought researchers at these three institutions together to explore and commercialize new technologies in proteomics.

When I came on board as Inproteo CEO last August, its success had already been well-documented. We've raised \$16 million in three years and spawned two start-up companies.

These collaborative efforts are critical to all three founding institutions of Inproteo. Lilly, for example, has spawned new start-ups like Maaguzi and Indigo just in the past several months. IU, Purdue and Lilly have worked with BioCrossroads to form the Indiana Centers for Applied Protein Sciences (INCAPS).

Companies such as INCAPS and the Inproteo spin-outs are an invaluable resource for our existing institutions that depend on this kind of specialized research but lack the requisite physical and staff infrastructure to perform internally. And having this new level of scientific research and innovation located in close proximity to one another is beneficial. A growing community of life sciences firms means more potential partnerships and a broader base of talent. All of these factors reinforce Lilly's commitment to complete \$880 million worth of life sciences construction in Indianapolis in the next five years and are a dramatic demonstration of the company's dedication to Indiana. It makes perfect business sense.

Inproteo is a great example of the collaborations that BioCrossroads is fostering for economic growth in Indiana. BioCrossroads was designed to support Indiana's existing life sciences industry and leverage this industry to create new businesses and jobs in Indiana.

So what should Inproteo do next? We are broadening our franchise beyond proteomics to include life science measurement technologies broadly conceived. We'd like to take our success in Bloomington and West Lafayette on to the Indiana University School of Medicine, and there are possibilities at other universities as well as at other companies. We'd like to explore relationships around the state, fitting technology sources to technology homes.

It's an exciting time to be involved in life sciences in Indiana, and I am proud to be a part of it now – and in the future.

New Alliances for BASi in 2006

BASi and Pipeline Biotech of Copenhagen, Denmark have formed a corporate alliance whereby the two contract research organizations will offer complementary services. BASi is focused on in-life safety and pharmacology assessment of new drug substances with a small molecule focus. Pipeline Biotech has a focus on pharmacokinetics (PK) and pharmacodynamics (PD) in vivo studies providing tailor-made pharmacokinetic research for biotech and pharmaceutical companies. The firm is an active partner in pre-clinical development for more than 50 international companies.

The location of Pipeline Biotech in Northern Europe not only enhances the capabilities of the BASi bioanalytical laboratory in the UK, but is convenient for the company's overall global development strategy. This alliance is especially important because there is increased interest in monitoring the safety and effectiveness of drugs by examining no-stress pharmacokinetics and safety profiles of clients' lead candidate compounds. (More about Pipeline Biotech at www.pipeline-biotech.dk.)

Earlier this year, BASi announced a contract research partnership with MicaGenix of Greenfield, Indiana encompassing complementary preclinical research services for pharmaceutical, medical device and biotechnology companies, as well as for medical schools.

MicaGenix has a strong focus on mutagenicity work, histopathology services, and regulatory package preparation and review. BASi provides contract research services generally downstream from MicaGenix in pharmacokinetics, pharmacodynamics, in vivo toxicology and clinical trials. There is very little overlap between the two companies' skill sets, and there are a number of opportunities to collaborate for the benefit of clients, especially the larger number of small discovery biology companies. (More about MicaGenix at www.micagenix.com.)

Also earlier in 2006, BASi and INCAPS (Indianapolis, Indiana) established a corporate alliance whereby the two contract research organizations will offer complementary services. INCAPS offers multiple mass spectrometry technologies, coupled with proprietary sample preparation methods and quantification software and has a focus on proteomics and protein characterization studies using current and emerging technology platforms, while BASi is focused on in-life safety and pharmacology assessment of new drug substances with a small molecule focus.

INCAPS has state-of-the-art instrumentation, informatics and statistical analysis tailored toward discovery biology and biomarkers, and the partnership offers one-stop shopping for large- and small-molecule work, which is an increasingly important part of what clients require. It allows both companies to respond to the increased interest in monitoring the safety and effectiveness of drugs by examining proteomic responses to chronic and acute dosing. (More about INCAPS at www.indianacaps.com.)

Happy birthday, FDA! Blow out 100 candles and make a wish for the next 100.

June 2006 marks the 100th anniversary of the FDA. Anyone involved in development of drugs and medical devices will benefit from the excellent effort the FDA has made to celebrate the centennial with historic information on the special anniversary web site: <http://www.fda.gov/centennial/default.htm>. There is a fun quiz you can take, and you can learn about the interesting characters involved in the process, including Harvey W. Wiley, a hero of the Purdue Chemistry Department here in West Lafayette, Upton Sinclair who dramatically reinforced Wiley's goals by exposing abuses in his best seller *The Jungle*. Teddy Roosevelt signed the legislation into law creating the FDA, but this was just a start. Along the way, tragedy after tragedy and abuse after abuse led to further embellishments

decade by decade. Some of this evolved from ignorance, some from neglect, some from bad or even fraudulent science and some from a poor balance between financial interests and public interests. A century later, the picture is much improved. Nevertheless, we continue to argue about exactly the same things: cost vs. speed; speed vs. quality; financial gain vs. improved health; rights of patients vs. physicians vs. companies; and broccoli vs. junk food. These debates will never end, nor should they. The debate is itself healthy.

New Executive Director of Clinical Operations at BASi



Patrick R. Ayd has been appointed Executive Director of Clinical Operations for the BASi clinical research unit in Baltimore, Maryland. He will be responsible for all phases of that operation, including the Company's new state-of-the-art first-in-man research unit, a 10-bed facility that allows intensive monitoring of

study participants including cardiac monitoring, blood pressure and O₂ with central monitoring and observation using the Philips comprehensive cardiac monitoring system.

Before coming to BASi, Ayd was Vice President of Operations at SNBL Clinical Pharmacology Center and headed the design and start-up of their 100-bed clinical pharmacology research center in Baltimore. Prior to that, he was Senior Director and Unit Head at Parexel-Baltimore, where he started a Phase I/IIa Clinical Pharmacology unit, overseeing its development from design through completion.

Mr. Ayd earned a B.S. in nursing from the University of Maryland and an MBA from Loyola College, The Sellinger School, and also received two post-graduate fellowships to study change management from Wharton Executive Education and Wharton School of Business. He began his career in the hospital field, working first as a nurse, then as a nurse manager, and Director of Patient Care Services, all paving the way for his move to operational management in the clinical research field.

Meetings and Conferences

11th ISEC 2007

The Eleventh International Seminar on Electroanalytical Chemistry will be held in Changchun, China, August 20 – 23, 2007. Since 1987 when the first ISEC was held under the auspices of the Chinese Chemical Society (CCS) and the Chinese Academy of Sciences (CAS), ISEC has been held every two years in Changchun, a beautiful city in the northeast of China. The aim of the meeting is to provide a forum for all electroanalytical chemists in the world to discuss their recent findings and mutual interests, to exchange information, and to promote international friendship and cooperation.

The meeting is organized on behalf of CCS and CAS, mainly by the Open Laboratory of Electroanalytical Chemistry in the Changchun Institute of Applied Chemistry of the CAS. For more details and the latest information, visit <http://www.skleac.org/>.

RDPA 2007

The 12th international meeting on Recent Developments in Pharmaceutical Analysis will meet on the Island of Elba, Italy, September 23 – 26, 2007. The aim of the RDPA meeting series is to provide a forum for high-level exchanges among scientists from universities, industries and government institutions who are involved in all aspects of pharmaceutical and biomedical analysis.

The meeting will offer a full overview of advanced trends in methodologies, applications and instrumentation in pharmaceutical and biomedical analysis. Contributions are invited from all areas of pharmaceutical and biomedical analysis, including those from emerging domains or more traditional topics. Papers presented will be considered for publication in a special symposium issue of the Journal of Pharmaceutical and Biomedical Analysis.

For more information: www.rdpa2007.com or secretariat@rdpa2007.com

DM-BNFL-2006

As a part of the Golden Jubilee year celebrations of Bhabha Atomic Research Centre (B.A.R.C.), a two-day discussion meeting on "Role of Electrochemistry in Biosensors, Nanomaterials, Fuel Cells and Ionic Liquids (DM-BNFL-2006)" is being organized by the Indian Society for ElectroAnalytical Chemistry (ISEAC) during September 24-25, 2006 at Multipurpose Hall, BARC Training School Hostel & Guest House, Anushakti Nagar, Mumbai-400 094. The objective of this meeting is to provide a forum for scientists and engineers to discuss the role of Electrochemistry in Biosensors, Nanomaterials, Fuel Cells and Ionic Liquids and the emerging trends in these areas. The Scientific program of the meeting will consist of Invited talks by Eminent scientists / engineers and contributed papers which will be presented in oral/poster sessions. Registration deadline is August 15, 2006. Visit www.iseac.org for complete information.

DESI Short Course

A two-day course on desorption electrospray ionization is being presented at Discovery Park, Purdue University, West Lafayette, Indiana, by the Office of Naval Research, Prosolia, Inc. and Bioanalytical Systems, Inc. Lectures and demonstrations will cover many DESI applications including:

- *Tissue imaging*
- *Drug screening*
- *Analysis of biomolecules*
- *Explosives detection*
- *Environmental contaminants*
- *Quantitation*
- *Use with fieldable mass spectrometers*
- *Drug and disease metabolites*
- *Ion-molecule reactions*

Attendees will also have the opportunity to do hands-on experiments. Plan to arrive by 6 p.m. on October 9, and depart at 3 p.m. or later on October 11, 2006. The \$150 fee includes lunch on Tuesday and Wednesday. Lodging at the Union Club Hotel at the Purdue Memorial Union not included.

For more information: discoverypark.purdue.edu, www.prosolia.com or www.chem.purdue.edu/cooks, or contact Brandy Houmes (dunlap@purdue.edu)

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In vivo sampling? Do it in your sleep. Really!

The Culex APS operates unattended 24/7. You as the user define collection times and sample volumes with Culex software interface. Set it and let it go. Have dinner, go to the movies, watch your children play soccer, get a good night's sleep, and all the while your Culex is dosing, sampling and simultaneously monitoring behavior and performing microdialysis for PK/PD correlations. That and much more.

How can you expect good data if your subject is stressed?

Imagine your reaction if some gigantic creature picked you up and forced some nasty-tasting stuff down your throat. How would your body react? The effects of stress on animals (of all species and sizes) are well documented. Think about it. We did. Research has shown that the stress associated with conventional blood sampling from rodents often has substantial effects on neurotransmitters, hormones, behavior and pharmacokinetic parameters. Thus, we determined that human handling of lab rats (and other animal subjects) results in inferior quality data.

Relax . . .

We found a way to sample freely-moving awake animals (rats, guinea pigs and, yes, even mice) without causing data-distorting stress. An implanted catheter is affixed to a tether assembly mounted to a counter-balanced arm that keeps the catheter from the animal's reach and view. The animal is free to move around inside a movement-responsive cage called a Ratum®, eliminating need for a liquid swivel. Once the animal is installed, dosing via IV, gastric or duodenal catheters can occur, and infusions, both bolus and continuous, can be programmed with an optional accessory, the Empis. All this is accomplished automatically, with no human-animal interaction.

It's about better science.

Multiple experiments can be performed in parallel, which means using fewer animals.

Data gathered via Culex are more accurate, precise and cost-effective, and offer unprecedented ability to correlate PK/PD results directly. For example, Culex can simultaneously monitor pharmacokinetics, neurotransmitter pharmacodynamics, rotational and rearing behavior, metabolism (urine and feces), and even

electrocardiograms. Researchers can now conduct humane, pain-free complete bioavailability studies using conscious, freely-moving rodents.

It's about time!

Better data in less time is a constant goal of the pharmaceutical industry. Experiments performed in parallel rather than in a series is one way to meet this goal. Having studies progress 24/7 without human involvement is cost-effective and

also saves time. And it's done with the utmost confidence that doses were delivered on time, all the samples were taken and no animals were missed. These, along with dose size, length of sampling time, and more, are completed automatically and detailed reports are produced. After a relaxing evening, the researcher returns to the lab the next morning to find a comprehensive report of everything that took place the night before. It's about time!



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