Committee on Oversight and Government Reform

Subcommittee on Government Organization, Efficiency and Financial Management

September 19, 2012

Written Testimony

Marc L. Rothstein

President, Prime Synthesis

Thank you Mr. Chairman for this opportunity to testify before the committee regarding the effectiveness of Trade Adjustment Assistance for Firms (TAAF). I am one of the founders of Prime Synthesis, Inc. and have served as its President for the past 12 years. Prior to that I performed the function of Chief Operating Officer. In both capacities, I was involved in all phases of management and strategic planning for the company.

My qualifications include an MSc Degree in Chemistry, followed by numerous MBA courses and specialized corporate training courses in business and upper management techniques. My career has included over 15 years of research positions in the Pharmaceutical, Chemical Process Instrumentation and Scientific Instrumentation industries. This was followed by another 12 years of business experience in the Scientific Instrument industry. During this time, I served as an Applications Chemist, Marketing Manager, Sales/Marketing Manager, Product Manager and finally Division Manager for The EG&G Princeton Applied Research Corporation.

This varied range of experience was applied to the start-up and management of Prime Synthesis, Inc. (PSI), a 24 year old company with 15 employees located in Aston, Pa. PSI manufactures advanced biotechnical materials and sells them to a global market. Its primary product is used to produce synthetic DNA (oligonucleotides) used for research, medical diagnostics and a new class of drugs. This product, called Controlled Pore Glass (CPG), has been considered the gold-standard for the application until about 7 years ago, when a new type of material was developed by two different companies located in Sweden (Pharmacia) and Japan (Nitto Denko). These new products were based on polymers instead of glass and for many oligonucleotide syntheses can achieve a greater yield and lower cost than that of CPG. Within two years of introduction, these competing products began to erode Prime Synthesis' market share, sales and profits.

In response to this competition, Prime Synthesis began a research program to develop a next-generation product (HybridCPG) that combined the advantages of CPG with those of the new polymer materials. Although some research grants were awarded by the NIH and IRS for this project, financial pressures due to business competition limited the available R&D budget. During this project, it became apparent that HybridCPG possessed some unique properties which

would allow its use in another very lucrative area of drug manufacture not previously addressed by Prime Synthesis, the purification of antibody drugs. Unfortunately, limited funding also negatively impacted both the market and scientific research needed to address this additional application.

In 2010 Prime Synthesis applied to the Mid-Atlantic Trade Adjustment Assistance Center (MATAAC) for a grant to help offset revenue losses due to foreign competition. A preliminary business review of PSI was conducted and MATAAC confirmed that the development and introduction of HybridCPG was the correct strategy to respond to the global competitive challenges the company faced. The MATAAC consultant worked with our management team to identify some key activities for implementing and accelerating this strategy. The activities included:

1. Securing patents for the HybridCPG concept and methods.

2. Accelerating the R&D for the HybridCPG project utilizing consultants in the areas of chemical design and engineering.

3. Securing a leading oligonucleotide production and testing company to help evaluate the prototype products.

4. Obtaining “Technology Driven Market Intelligence” to confirm and characterize the new market opportunity for antibody drug purification.

During 2011 and 2012 significant progress was made due to the partial funding of these activities through the MATAAC Grant. This includes the following milestones:

1. International patents will be issued for the HybridCPG by the end of 2012.

2. Fundamental advancements in the new product design were developed through work with an expert technical consultant.

3. One of the largest oligonucleotide production testing companies in the world was funded to evaluate HybridCPG prototypes. Based on their positive results over 20 field trials are being conducted to demonstrate the performance advantages of HybridCPG.

4. The Delaware Valley Industrial Resource Corporation, a member of the Manufacturing Extension Partnership initiative of the National Bureau of Standard Technology, identified and helped to set up a market research/business opportunity study. This was conducted by the Research Triangle Institute and was partially funded by the MATAAC Grant. The results of this study have enabled the business plan for expansion of PSI into the antibody purification marketplace that could represent an additional $100 Million in revenues over the next 5 years.

The progress represented by the above milestones has allowed PSI to enter into negotiations with several large corporations that could be potential partners to further accelerate commercialization

of the HybridCPG technology. It is also using this information and progress to attract both private and commercial investors to further facilitate the expansion and development of the company.

In summary, the combination of expert advice and funding provided by MATAAC will enable PSI to defend its business against foreign competition and become a much larger biotech company, creating many new jobs while lowering the manufacturing costs for two new classes of pharmaceutical products aimed at a variety of cancer and genetically transmitted diseases.

Again, I thank you for allowing me to be a part of this discussion.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Marc L. Rothstein	President
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Temple University, Philadelphia, PA	B.S.	06/74	Chemistry
Temple University, Philadelphia, PA	M.S.	06/78	Electrochemistry
Wharton School of Business at UPenn, Philadelphia, PA	Coursework	1990-1993	Marketing

A. Positions and Honors

Positions and Employment

1974-1979 Research Scientist - Leeds and Northrup Company, North Wales, PA
1979-1983 Applications Scientist - Electrochemical Instrumentation - EG&G Princeton Applied Research Corp, Princeton, NJ
1983-1988 Marketing and Sales Manager-Electrochemical Instruments - EG&G Princeton Applied Research Corp., Princeton, NJ
1990-1993 Division Manager - Electrochemical Instruments - EG&G Princeton Applied Research Corp., Princeton, NJ
1993- President - Prime Synthesis, Inc., Aston, PA

Other Experience and Professional Memberships

1974-1995 Member, American Chemical Society
1979-1995 Member, Electrochemical Society
1996 Recipient, Ben Franklin Technology Partners of Southeastern Pennsylvania –Emerging Growth Funding Award- Optimization of Controlled Porosity Glass for Solid Phase Oligonucleoside Synthesis
1993 Recipient, Ben Franklin Technology Partners of Southeastern Pennsylvania –Emerging Growth Funding Award- Development and Implementation of Large-Scale Process for Manufacturing Controlled Porosity Glass

B. Publications

Most relevant to the current application

1. Rothstein, M.L., *Advancements in CPG Synthesis Supports,* Tides 2000 Workshop, May 10, 2000.

2. Rothstein, M. and Phelan-Rothstein, D., *Lowering Solid Support Costs for Oligonucleotide Synthesis*. Poster Presentation at Tides, 2007, LasVegas.

3. Rothstein, M. and Phelan-Rothstein, D., *Recycling of Controlled Pore Glass (CPG) Solid Supports for Oligonucleotide Synthesis*. Poster Presentation at Tides, 2009, LasVegas, NV.

Other Publications:

1. Taylor, R., Phelan, D., and Rothstein, M., *Detailed Conceptual Design of a High Temperature Glass pH Electrode for Geothermal Applications; Report number PNL-3051*. 1979, US Department of Energy, Division of Geothermal Energy, under DOE Contract number EY-76-C-06-1830.

Committee on Oversight and Government Reform
Witness Disclosure Requirement – "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

Name: Marc L. Rothstein

1. Please list any federal grants or contracts (including subgrants or subcontracts) you have received since October 1, 2009. Include the source and amount of each grant or contract.

   SBIR Phase I Grant: NIH (NIGMS), A Novel Hybrid Solid Support for Cost-Effective, Large-Scale Oligonucleotide Synthesis, A Novel Hybrid Solid Support for Cost-Effective, Large-Scale Oligonucleotide Synthesis, 2009, $97,000.

   Qualifying Discovery Therapeutic Program (QDTP) Grant, IRS/NIH, Hybrid Support Technology, 2010/2011, $244,000.

   MidAtlantic Trade Adjustment Assistance Center (MATAAC) Grant, Dept. of Commerce, 2010, $100,000.

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

   Prime Synthesis, Inc.- Founder and President

3. Please list any federal grants or contracts (including subgrants or subcontracts) received since October 1, 2009, by the entity(ies) you listed above. Include the source and amount of each grant or contract.

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I certify that the above information is true and correct.
Signature: Date: