Innovation and Industry Services

Technology Innovation Program

2010 ANNUAL REPORT

National Institute of Standards and Technology • U.S. Department of Commerce

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We would like to extend our appreciation to the many proposers, TIP awardees, and authors of white papers whose creativity, vision, and passion for science and technology are vital to the continued advancement of U.S. leadership in innovation.

Deputy Director's Statement

The Technology Innovation Program (TIP) was created on August 9, 2007, as part of the America COMPETES Act (P.L. 110-69). Its purpose was to fill gaps within the national research spectrum by providing funding to leverage emerging research with the potential to create transformational impacts on the Nation's critical needs. Whether the challenge is, for example, inspecting the Nation's infrastructure, reducing carbon emissions, or accelerating the emergence of personalized medicine, TIP was designed to give the flexibility to leverage National Institute of Standards and Technology (NIST) expertise to complement the work of other agencies and broadly engage the scientific, technology, and policy communities to identify key unmet technical needs within these societal challenges.

TIP made a total of 38 awards to 78 different participants in 2008 to 2010. Awardees have leveraged TIP's commitment of $135.7 million investment in research awards with an additional $144 million in cost sharing, for a total of $279.7 million in research and development (R&D) dedicated to addressing technical challenges in the pressing national needs of civil infrastructure and manufacturing.

In December 2010, TIP announced nine new projects in the Manufacturing area of Critical National Need. During the performance period of these projects, TIP and its awardees will invest $45.9 million in R&D funds, including $22.2 million from TIP and $23.7 million in cost-shared funding. In early 2010, the twenty projects awarded in the 2009 Civil Infrastructure and Manufacturing competitions began work, and the nine civil infrastructure projects awarded from the 2008 competition continued.

TIP's 2010 work was accomplished under Lorel Wisniewski's leadership as the TIP Deputy Director and Acting Director. Dr. Wisniewski served as TIP's Deputy Director from its start until mid-2011. Her leadership kept the program focused on its core mission and enabled outreach to new communities of scientists and stakeholders.

TIP would like to recognize and thank the 2010 TIP Advisory Board for their insightful guidance over the course of the program. The TIP Advisory Board is a distinguished group of experts in the field of technology innovation, and is comprised of representatives of high-tech companies, the venture capital community, and universities. The 2010 Board includes Jeffrey P. Andrews (Chair), Senior Vice President of Strategy and Business Development of Advanced Electron Beams; Dr. Vinton G. Cerf, Vice President and Chief Internet Evangelist, Google, Inc.; Dr. Charles L. Cooney, Professor of Chemical Engineering, Massachusetts Institute of Technology; Dr. Mauro Ferrari, Professor of Internal Medicine, University of Texas; Dr. Martin Izzard, Vice President of Texas Instruments; Dr. Ray O. Johnson, Senior Vice President and Chief Technology Officer, Lockheed Martin Corporation; Dr. Radia Perlman, Intel Laboratories; Dr. Luis Proenza, President, University of Akron; James E. Reeb, former Director of Manufacturing R&D, Caterpillar, Inc.; and Dr. Willam Peter Teagan, Independent Consultant. The *2010 Annual Report of the Technology Innovation Program Advisory Board* captures their findings and recommendations. [1]

In FY 2011, the TIP appropriation did not provide for new awards, although funding was approved to continue fiduciary and administrative responsibilities. NIST received an appropriation for fiscal year 2012 when P.L.112-55 was signed by President Obama on November 18, 2011. However, no funding was included for the Technology Innovation Program. TIP is currently in the process of shutting down program operations, while continuing to provide project management for ongoing cooperative agreements that were fully funded at the time of award. This report addresses the status of TIP's cooperative agreements and lessons learned.

1 *2010 Annual Report of the Technology Innovation Program Advisory Board*, U.S. Department of Commerce, National Institute of Standards and Technology, Technology Innovation Program, March 2011. See <http://www.nist.gov/tip/adv_brd/upload/tip_advisory_bd_annual_rpt_2010.pdf>

To this end, as TIP continues with its orderly shut-down, it has an obligation to develop a system and processes that will document TIP's legacy and lessons learned. This system will preserve valuable information, which can be used by NIST and other federal agencies funding cutting-edge research to understand the best practices and outcomes of public-private partnerships.

The system is comprised of three broad areas:

- Continued due diligence in monitoring and oversight of TIP awards;
- Capturing, organizing, and archiving programmatic details; and
- Analyzing and communicating generalized findings and lessons learned.

Commitment to Continued Project Management

TIP's most lasting and important legacy will reside in the benefits the nation will receive from the research being conducted by the small- and medium-sized businesses and universities participating in TIP. It is critical that for the life of the existing TIP awards TIP maintains its relationship with these organizations, who have committed substantial resources of their own, to maintain an environment that maximizes the likelihood that the research of today translates into the solutions and benefits of tomorrow.

Capturing, Organizing, and Archiving Information

TIP has already implemented a process for capturing and archiving information describing important program elements. This information spans the history of TIP and includes everything from initial selection of areas of critical national need through summary reports of TIP's initial projects in Civil Infrastructure. Information being archived includes descriptions of the selection process and project management procedures, as well as project-related data collected from awardees and three customer satisfaction surveys administered to awardees from each of TIP's competitions. All information is being captured and organized in accordance with federal archiving requirements.

Analysis and Findings from TIP

In addition to properly maintaining all relevant information, TIP staff has been performing analysis of lessons learned and findings to date. We expect to share these analyses and findings with NIST management, other federal agencies, and the public through several publications. Topics include examining outcomes from projects funded early in TIP's portfolio, the impact of increased cost-sharing requirements for TIP projects as compared to requirements under the Advanced Technology Program (ATP), and the process of constructing portfolios of critical national needs.

I am personally proud to have been associated with TIP since its inception. Everyone at TIP is honored to have supported and worked with the dedicated and bright men and women conducting the cutting-edge research required to overcome technical barriers in monitoring and repairing our roads and bridges and implementing advanced manufacturing processes.

On behalf of my colleagues here at TIP, thanks to our awardees who have accomplished so much and to all of you who have supported our efforts.

Sincerely,

Thomas Wiggins

Deputy Director, Technology Innovation Program

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Executive Summary

Section 3012 of the America COMPETES Act (P.L. 110-69, codified at 15 U.S.C. 278n) requires the Technology Innovation Program (TIP) to "submit annually to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Science and Technology of the House of Representatives a report describing the Technology Innovation Program's activities, including a description of the metrics upon which award funding decisions were made in the previous fiscal year, any proposed changes to those metrics, metrics for evaluating the success of ongoing and completed awards, and an evaluation of ongoing and completed awards." This report fulfills the requirement for 2010.

In 2010, the Technology Innovation Program (TIP) continued in its mission of identifying and filling gaps in the Federal research spectrum. The program provided resources to leverage emerging research that addresses the Nation's critical needs. These needs challenge society's ability to respond to threats to the Nation's economy, environment, health, and safety. TIP addressed these needs by investing in innovative research projects that will provide technologies to solve these problems and by tracking prior investments to demonstrate early outcomes from funded research.

TIP fulfilled its mission by—

▷ Making awards to nine new Manufacturing projects that represent $45.9 million in high-risk, high-reward research. If successful, over the project lifecycles, participants will invest $23.7 million in cost-shared funding, matched with $22.2 million in Federal funds;

▷ Holding a competition in the Manufacturing area of critical national need, which received 110 submissions;

▷ Initiating the 20 projects awarded in the 2009 Civil Infrastructure and Manufacturing competitions;

▷ Supporting the meetings of the TIP Advisory Board, which provides valuable advice on program directions and, in 2010, discussed potential areas of critical national need, including Energy, Manufacturing, Advanced Automation and Robotics, and Ensuring the Nation's Water Supply;

▷ Supporting the publication of the first TIP Advisory Board report;

▷ Engaging the broader scientific and technical community through more than 20 outreach events;

▷ Soliciting outside white papers to suggest future possible directions for program investment, which resulted in 32 outside white papers received;

▷ Soliciting outside comment on TIP-prepared draft white papers, which resulted in 10 outside comments received;

▷ Surveying TIP applicants to improve the program; and

▷ Planning for surveys of TIP awardees to track the impacts of funded projects.

Section 1 of this Annual Report provides an overview of TIP. Section 2 discusses TIP's areas of investment in 2010, Manufacturing and Civil Infrastructure, including ongoing and new awards in those areas. Section 3 updates areas of critical national need that were under review for possible future solicitations. Section 4 reports on findings from TIP's Impact Analysis Office.

SECTION 1

What Is the Technology Innovation Program?

The Technology Innovation Program (TIP) provides cost-shared funding to speed the development of high-risk, high-reward, transformative research. This research targets key societal challenges not being addressed elsewhere.[2] TIP is part of the National Institute of Standards and Technology (NIST), headquartered in Gaithersburg, MD. TIP is strategically positioned to help U.S. businesses, institutions of higher education, and other organizations—such as national laboratories and nonprofit research institutes—to support, promote, and accelerate innovation in the United States in areas of critical national need. The TIP regulations[3] (TIP Rule) define a societal challenge as "a problem or issue confronted by society that when not addressed could negatively affect the overall function and quality of life of the Nation, and as such justifies Government attention."[4] TIP identifies societal challenges that require transformational technical results to address the underlying problems. TIP staff work with agencies across the Federal Government to ensure that TIP funds target those elements of societal challenges not otherwise being addressed.

Program funds may support only research that has scientific and technical merit, as well as strong potential for making state-of-the-art advances and contributing to the U.S. science and technology (S&T) base. The research must carry high technical risks—and commensurate high rewards if it is successful. The mechanism for this support is cost-shared cooperative agreements, awarded through merit competitions.

Features

The authorizing legislation established TIP's major features. The following are some highlights:

- TIP has a novel purpose. TIP awards funding for high-risk, high-reward research and development (R&D) projects that address the Nation's critical needs and societal challenges in areas not being addressed by others.

- TIP supports rich teaming. Projects may be proposed by individual small or medium-sized for-profit companies or by joint ventures that may include for-profit companies, institutions of higher education, national laboratories, nonprofit research institutes, or state or local agencies, as long as the lead member in the joint venture is either a small or medium-sized business or an institution of higher education.[5]

- TIP is a public-private partnership. TIP makes cost-shared awards of up to 50 percent of total project costs. TIP may award up to $3 million in total direct costs over 3 years for a single-company project or up to $9 million over 5 years for a joint venture project.

- TIP supports small and medium-sized businesses. Large businesses may participate in a TIP-funded

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[2] TIP was created on August 9, 2007, as part of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act (America COMPETES Act), P.L. 110-69.

[3] 15 C.F.R. Part 296.

[4] 15 C.F.R. § 296.2.

[5] Full information on the requirements of TIP joint ventures and eligibility issues for project teaming arrangements can be found on pages 3 to 5 of the Technology Innovation Program Proposal Preparation Kit, April 2010, available at http://www.nist.gov/tip/cur_comp/upload/tip_preparation_kit_2010_complete_a.pdf

project, but they may not receive TIP funding as a recipient or subrecipient.

- TIP complements—but does not duplicate—existing R&D efforts. TIP funds R&D not already being addressed, for which other funding (public or private) is unavailable, and for which Government support is justified. TIP staff work with other agencies to ensure that TIP competitions are in areas not being addressed by other Federal agencies. In addition, TIP works closely with the private sector to understand where private resources are unavailable.

- TIP contributes to the U.S. knowledge base. For single awardees, the awardee owns intellectual property pursuant to the Bayh-Dole Act. For joint ventures, title to any intellectual property created through TIP awards vests with the participants in the TIP project pursuant to their joint venture agreement.

- TIP is part of the U.S. innovation system. TIP's purpose is to assist all participants in the innovation system to support, promote, and accelerate innovation in the United States.

- TIP assesses its progress and results. TIP uses state-of-the-art evaluation and assessment techniques to ensure optimal performance and results. An external TIP Advisory Board provides advice on programs, plans, and policies.

- TIP is part of NIST. NIST—the U.S. Government institution for advancing measurement science, standards, and technology—provides TIP with a rich innovation infrastructure, consisting of groundbreaking research conducted by world-class scientists and engineers.

In addition, TIP has supported small, young companies. Of the 38 proposals funded by TIP, 14 projects (approximately 37% of total projects funded), involved small companies less than five years old. These small, young firms tended to be very small. On average, each firm employed just over 10 people. This impact was even more pronounced in TIP's final competition in 2010 where 6 projects (approximately 67% of total projects funded), involved participation by small companies five years old or less.

SECTION 2

Addressing the Nation's Critical Needs

In December 2010, TIP announced nine new awards in the Manufacturing area of critical national need. The funded projects represent $22.2 million of projected TIP funding over the life of these awards, matched with $23.7 million of cost-shared funding from the project participants, totaling $45.9 million in high-risk, high-reward research. These nine single company projects include 19 entities participating as single company leads, subrecipients, or contractors. The contractors and subrecipients are companies, universities, or other entities. The 19 entities are located in 11 states, demonstrating the geographic diversity of the awardees that were interested in these topic areas.

In 2010, TIP received 110 proposals seeking $314.6 million in funding and offering to contribute an additional $331.6 million in cost share for proposed projects. This widespread interest in the 2010 competition demonstrates the engagement of the technical community with TIP.

Combining the 2010 awards with TIP's prior awards, TIP is now managing a portfolio of 38 projects. The 38 funded projects have 132 participants, including single-company leads, joint-venture members, subrecipients, and contractors.

New Projects Awarded in 2010: Manufacturing

The projects awarded in TIP's second Manufacturing competition began work in early 2011.

Manufacturing has a rich history and has long been a significant part of the American economy. The United States is the world's leading producer of manufactured goods. As the Administration's "A Framework for Revitalizing American Manufacturing" states:

> The manufacturing sector generates significant benefits for society. Manufacturing creates substantial additional economic activity, is responsible for 70 percent of all research and development spending performed by industry in the United States, and with consistently improving productivity creates wealth that can be utilized elsewhere in the economy. Manufacturing jobs have higher pay and benefits than similar jobs in other sectors. Manufactured goods represent 69 percent of exports, which is particularly important as increasing exports is critical to reducing our trade deficit and supporting economic growth.[6]

Transformative research often achieves broad national impact only through incorporation into manufactured products. To preserve this element of the U.S. economy, the manufacturing sector will need to continue implementing technology advancements in the coming years.

In 2010, the Manufacturing topic selected was *Manufacturing and Biomanufacturing: Materials Advances and Critical Processes.*[7] The solicitation

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[6] "A Framework for Revitalizing American Manufacturing," Executive Office of the President of the United States, December, 2009 available at http://wts903.nist.gov/mep/pdf/20091216-manufacturing-framework-final_embargoed.pdf

[7] Details of this solicitation topic are available in the Federal Funding Opportunity notice at http://www.nist.gov/tip/upload/2010_ffo_competition_amend_0610.pdf. The TIP white paper describing this area is available at http://www.nist.gov/tip/cur_comp/upload/manufacturing_biomanufacturing_matls_adv_crit_proc_04_2010_wp.pdf

required that proposals address at least one of its three specific subtopics:

- **Element 1—Process scale-up, integration, and design for materials advance**s
  New materials typically are developed in a laboratory setting, and then samples are given to end-users for alpha and beta testing. During this testing phase, it can take considerable time and experimentation to understand how the materials can be incorporated into a new product in a way that maintains and utilizes their unique functionality.[8] Scaling-up from laboratory quantities to larger volumes, validating properties, and then incorporating the materials into product manufacturing lines is often nonlinear and does not follow straightforward scaling laws, due to the unique functionality that has been obtained from the materials advances.

- **Element 2—Predictive modeling tools for materials advances and materials processing**
  Predictive modeling capabilities are key to developing new processes, scaling-up these processes, and understanding how to utilize the unique functionality of materials advances. Modeling capabilities are needed principally to:

  - Analyze and understand why newly discovered materials do what they do and then extrapolate their behavior to new uses; and

  - Incorporate this knowledge more efficiently into process design tools so new products can be made while maintaining the unique functionality of the materials as predicted.

- **Element 3—Critical process advances**
  As the availability of new materials increases and the modeling of their behavior becomes more refined, there is a complementary need to improve processing or manufacturing methods. High-risk, high-reward approaches are needed to exploit the properties of the materials advances into new and more advanced products as well as support the processing of existing materials in new and different ways, resolving key bottlenecks or critical problems such as energy consumption, processing time, scrap rates, quality, and throughput. Current methods of manufacturing often are not rapidly adaptable to making new or different products, and are often not optimized toward making existing products faster, cheaper, and more sustainably. Improving processes used in the manufacture of new and existing products is imperative for the continued global competitiveness of U.S. manufacturers. Agile, flexible, and increasingly interoperable systems are necessary enhancements to base manufacturing technologies in order to meet new productivity challenges.

Significant biomanufacturing process improvements are needed to enhance safety, quality, and consistency of biopharmaceuticals while reducing the manufacturing cost. For example, current sensing technologies typically require manual sampling, are not rapid or robust to cleaning agents or processes, and are not sufficiently reliable for imbedding in the manufacturing environment as automated technology. Critical process advances are needed, enabling rapid on-line sensing and analytical capabilities. New tools are needed for bioprocess optimization, control, and improvement to enable a cost-effective batch or continuous manufacturing process. Processes that involve integrated sensing and detection capabilities for measuring multiple parameters will be useful. Moreover, purification and separation process advances involving novel

[8] Note that proposals with the principal focus on discovering new materials were considered nonresponsive to the scope of the competition.

membranes and affinity reagents are needed for cost-effective downstream processing in biopharmaceutical manufacturing processes.

Proposals addressing the first two elements of the solicitation were required to apply the technology chosen to at least one of five classes of advanced materials: (1) nanomaterials; (2) composites; (3) alloys, superalloys, and smart materials; (4) ceramics; or (5) glasses.

The first two elements also were part of TIP's 2009 Manufacturing competition and were chosen because materials performance is often a critical consideration and controlling factor in innovation.[9] The classes of materials were expanded in 2010 to include ceramics and glasses. Ceramics have new uses in improving electronic and photonic devices that are critical for alternative energy applications, and glasses have many next-generation applications such as wireless communication, displays, optical telecommunication, integrated circuits, and ion exchange membranes for fuel cells. Development of sustainable advanced materials and advanced materials with new properties are critical to ongoing or increased competitiveness of U.S. innovations.

The third element, critical process advances, was new in 2010. Process improvements made through high-risk, high-reward research and development, rather than simple engineering improvements or redesign, could lead to significant and quantifiable improvements in measures of process output. Critical process advances require modifications in manufacturing that augment and expand current limited capabilities. Applications could include creating novel methods to fabricate unique components from complex, difficult-to-machine materials (i.e., advanced engineering materials or smart materials), or designing and implementing real-time, sensor-based, feedback-optimized systems for discrete, continuous, or batch manufacturing. An example of discrete manufacturing could be a process for making customized parts like medical implants, using techniques such as additive manufacturing, near net-shape fabrication, or partial forging. Processes are needed for manufacturing parts possessing complex geometries from existing and novel materials while preserving the properties of the material. A batch-process example would be improved process monitoring and in situ analytical tools, reducing batch-to-batch variability and improving quality, and a quantity of biopharmaceuticals or other products produced more reliably and cost-effectively.

Biomanufacturing was a new application area, added in 2010. Biomanufacturing here refers specifically to the manufacturing of biopharmaceuticals. Biopharmaceuticals are complex pharmaceutical products manufactured using biotechnology. Two types of biomanufacturing were considered: bioprocessing for biopharmaceuticals such as recombinant proteins for vaccines, therapeutics, or molecular probes for diagnostics; and advanced biofabrication and processing to produce cell- or tissue-based biopharmaceuticals such as engineered cells and engineered tissues for therapies. Engineered tissues are complex structures involving cells, scaffolds, and signaling molecules. Manufacturing of either type of biopharmaceuticals was within the scope of the competition. For example, consider the response of vaccine production to the H1N1 flu outbreak in 2009. Experts were able to decode the virus to prepare a vaccine in record time, but encountered problems in supplying the large volumes

[9] Integrated Computational Materials Engineering: A Transformational Discipline for Improved Competitiveness and National Security (Committee on Integrated Computational Materials Engineering, National Research Council, 2008), http://www.nap.edu/catalog.php?record_id=12199

of vaccine needed quickly. Vaccines are grown in chicken eggs in a process that dates back to World War II. Each egg is in effect its own factory, with product variability and purity issues. Development of new processes for production of recombinant vaccines, as well as processes for real-time monitoring and analysis, could address these problems, and would not only help to respond rapidly to new virus outbreaks but could also reduce the cost of clinical trials through better methods to scale-up.

Three of the awarded projects planned research in the scale-up of advanced materials (Element 1) and six planned research in critical process technologies (Element 3). Five projects across both Element 1 and Element 3 were in the biomanufacturing area. More details on the TIP-funded projects are available in the abstracts in the Appendix.

Ongoing Projects: Manufacturing

During 2009, TIP announced its first competition relevant to the Manufacturing area of critical national need. TIP received 63 proposals[10] in Manufacturing and awarded 12 projects. These projects started in February 2010. Over the life of these awards, the 12 projects will leverage $40.9 million of Federal funds with $42.9 million of cost-shared contribution, for a total of $83.8 million invested in research addressing the challenges of manufacturing advanced materials. These projects include 4 joint ventures with a total of 12 joint venture partners and 8 single-company projects.

The selected proposals in Manufacturing addressed both technical areas featured in the 2009 competition: process scale-up integration and design (11 projects) and predictive modeling (1 project). All three material types called out in the 2009 competition are represented in the 12 projects: nanomaterials (6 projects); composites (4 projects); and alloys, superalloys, and smart materials (2 projects).[11]

TIP's project management teams have performed kickoff meetings with project participants, as well as subsequent annual site visits. In addition, TIP's project management teams continually monitor these projects through quarterly technical and impact reports, as well as financial reports, to ensure compliance with the award terms and conditions and to engage in valuable technical discussion with the project participants. TIP proactively identifies project management issues and works with recipients and through the NIST Grants Officer to resolve them.

Ongoing Projects: Civil Infrastructure

TIP has conducted two award competitions, one in FY 2008 and one in FY 2009, in the area of Civil Infrastructure. These awarded projects involve research addressing advanced sensing and repair for the Nation's physical infrastructure.

In FY 2008, TIP conducted its first competition in Civil Infrastructure--"Advanced Sensing Technologies for the Infrastructure: Roads, Highways, Bridges, and Water Systems."[12] The competition called for implementable, usable, and accurate sensing systems for effectively measuring infrastructure performance. TIP selected 9 of 46 proposals submitted for this competition for award. TIP announced the awards on January 6, 2009. The 9 projects include $42.5 million

[10] Of the 138 proposals received by TIP in 2009, 25 were nonresponsive and addressed topics other than Civil Infrastructure or Manufacturing.

[11] Proposals are assigned to technical areas and classes of materials based on the primary area and primary class of material addressed in the proposal. Many proposals related to the scale-up, design, and integration of processes included some work in predictive modeling. Similarly, several proposals indicated plans to move beyond a primary material class to other materials in the future.

[12] http://www.nist.gov/tip/prev_competitions/upload/cnn_white_paperfinal.pdf

in TIP support and $45.7 million in matching cost-shared funding for a total of $88.2 million in R&D.

In FY 2009, TIP expanded its portfolio of Civil Infrastructure projects with its second competition—"Advanced Sensing Technologies and Advanced Repair Materials for the Infrastructure: Water Systems, Dams, Levees, Bridges, Roads, and Highways."[13] The expanded scope of this second competition included new technologies for repairing and retrofitting existing structures and extended the definition of structures to include dams and levees. TIP selected 8 of 50 proposals submitted for this competition for award. The awards were announced December 15, 2009. These 8 projects represent $30.1 million in TIP support and $31.7 million in cost-shared funding for a total of $61.8 million in R&D.

Awarded projects from the first two Civil Infrastructure competitions demonstrate TIP's commitment to multidisciplinary approaches and to encouraging broad teaming arrangements. Fifty-one research participants are involved in the 17 awarded projects. Over the life of these 17 projects, they will receive up to a total of $72.6 million of TIP funds and will contribute $77.4 million in cost-shared funding, for a total investment of $150.0 million in new R&D. These awarded projects address multiple areas: inspection and monitoring technologies (13 projects) and repair and retrofit technologies (4 projects). The projects also address various structures and types of pavement (2 projects), bridges (9 projects), water and wastewater systems (6 projects), and dams and levees (1 project). Some projects address more than one type of structure.

TIP's project management teams have continued to proactively manage these projects, including reviewing quarterly financial, technical, and impact reports and holding annual site visits.

[13] http://www.nist.gov/tip/prev_competitions/upload/ci_wp_031909.pdf

SECTION 3

Developing and Selecting Areas of Critical National Need

TIP implements the program's mission to respond to critical national needs by identifying opportunities to fill gaps within the federally funded research spectrum. These gaps represent opportunities for accelerating innovation in new, often multidisciplinary, areas. In 2010, TIP used a pipeline of critical national needs, pursuing a series of different areas and prioritizing topic areas for investment depending on the criticality of the issues and the availability of funding. In developing its pipeline of critical national needs, TIP applied consistent measures that allowed for the comparison of different topic areas. In this way, TIP could leverage high-risk, high-reward technology to meet unaddressed societal challenges. This pipeline enables TIP to have a number of areas researched and ready to develop into solicitations.

Process Overview

TIP used a multistage process to establish a pipeline of areas of interest for investment in critical national needs for 2010. Distinguishing elements of this process were the use of experts at key stages and consistent technology-neutral metrics to evaluate different potential topic areas. The metrics are provided below:

- Mapping to Administration Guidance
  - To national objectives
  - To NIST's areas of technical competence
  - To the TIP purpose
- Justification for Government Attention
  - Magnitude and nature of the problem
  - Societal challenge(s) unmet by others
  - Evidence of commitment of each award participant to enable or advance the transformation of the proposed research results
- Essentials for TIP
  - Expands scientific frontiers
  - Meets a timely need unmet by others
  - Has potential for impacts and transformations
  - Fosters high-risk, high-reward research

TIP's metrics allow the TIP Director to systematically evaluate diverse areas and challenges and make investment decisions. For example, to address "Mapping to Administration Guidance," TIP used direction from the Office of Science and Technology Policy annual budget priority memos,[14] which listed the Administration's key areas for research investment. The evaluation considered how well the critical national need fit within NIST's areas of technical competence and TIP's purpose. In examining the need for Government attention, TIP addressed the magnitude and nature of the problem and the extent to which societal challenges were unmet by others.

Finally, the alignment with TIP's purpose examined

[14] See "Science and Technology Priorities for the FY 2012 Budget," Memorandum from Peter R. Orszag, Director, Office of Management and Budget, and John P. Holdren, Director, Office of Science and Technology Policy, July 21, 2010, available at http://www.whitehouse.gov/sites/default/files/microsites/ostp/fy12-budget-guidance-memo.pdf

the potential for the investment area to stimulate work on scientific frontiers, meet a timely need not met by others (public or private), deliver impacts and transformations, and foster high-risk, high-reward research.

A critical part of TIP's pipeline development work was analyzing other Federal funding in a given area and the unique role that TIP could play in addressing the critical national need and the societal challenge of that area. By conducting this gap analysis, TIP could identify specific avenues of research within a critical national need area complementary to other agencies' core missions. To be successful, a program like TIP must demonstrate knowledge of what other agencies are doing and show that the programs are complementary.

In 2010, TIP examined various inputs regarding critical national need areas. Potential topics came from white papers submitted to the program, Government agencies' resources and scientific experts, as well as respected scientific organizations (such as the National Academies), the Science and Technology Policy Institute (STPI), the TIP Advisory Board, industry organizations, leading researchers from academic institutions, the NIST laboratories, and others. TIP also leveraged nationally recognized science and technology reports, industry roadmaps of technology needs, and other sources such as studies from the National Academies.

TIP Advisory Board meetings usually included a lengthy discussion of at least one area of critical national need under consideration. At the May 11, 2010, meeting, several speakers addressed advanced automation as a potential critical national need area. Advanced automation includes technologies such as sensing, signal processing, artificial intelligence, modeling, and control systems, all of which are important enablers for adopting new products and technologies in markets ranging from manufacturing to care for the elderly. Agriculture is another potentially important application for advanced automation. Designing a robot to pick apples, for example, is a difficult challenge. The speakers emphasized that advanced automation technology can improve safety and effectiveness, and therefore, the commercial viability of a wide range of new products.

A second topic discussed at the May 11, 2010, meeting was ensuring the Nation's water supply. Issues concerning water as a critical national need were addressed, including discussion of potentially innovative ideas and the opportunity for TIP to make a difference. The private sector has traditionally not invested heavily in research in water processing.

At the November 2, 2010, meeting, the TIP Advisory Board's main topic was the smart grid NIST is playing a key role in standards-related issues associated with the smart grid. For this topic, TIP was collecting input from industry and other agencies and exploring whether the smart grid might qualify as a critical national need.

To complete the evaluation process, TIP established working groups to refine potential topics for the TIP Director's initial evaluation against the metrics described above.

Critical National Need Choices and Potential Areas of Interest

The following sections discuss each area of critical national need under consideration in 2010.

Civil Infrastructure

The construction industry and its material suppliers generally do not pursue long-term research objectives. The industry focuses on short-term R&D, which yields modest improvements in products and permits rapid introduction into and acceptance by the marketplace. This short-term R&D focus produces incremental improvements, but it does not allow for the significant advances in construction materials that could revolutionize the industry with superior mechanical and physical properties, higher quality, faster construction, and fewer maintenance requirements. New materials and process advances are needed to energize the U.S. design and construction industry, providing a competitive advantage through advanced technology and providing tangible economic benefits through market expansion and creation. These developments come from longer-term, high-risk, high-reward R&D that leads to novel solutions that may revitalize and improve our Nation's infrastructure and dramatically increase the competitiveness of the U.S. construction industry and its material suppliers.

Next-generation construction materials and processes will need to be substantially more flexible and green than current construction materials so that future infrastructure materials will have enhanced *durability, safety,* and *sustainability.* A model of the next-generation construction materials and processes includes a combination of four platform technologies. The four platform technologies or themes include the following:

▷ Engineered nano/microstructures;

▷ Multifunctional materials and systems;

▷ Nano/micromanufacturing; and

▷ Self-healing/self-monitoring materials.

The next-generation materials and processes could allow the construction industry to move toward structural element production with higher speeds, improved quality control, faster assembly, and less impact on the environment. It could also usher in a more resilient civil infrastructure with the capacity to withstand natural and manmade disasters, with lower maintenance, while increasing service life. This would result in a future "built" environment more in harmony with the natural environment. Focused research on next-generation construction materials and processes will require cross-disciplinary collaboration between material scientists and engineers, specializing in multidisciplinary areas including materials science and engineering, manufacturing processes, nanotechnology, mechanical design, industrial ecology, and structural engineering. Development of next-generation technology of construction materials and processes will help strengthen the Nation's commercial competitiveness while providing better safety, security, and quality of life to its citizens.

Complex Systems and Networks

Our national infrastructure depends on such complex networks as those for energy, telecommunications, manufacturing, transportation, biology, and finance systems for which there is imperfect understanding and control. No single organization and no collection of organizations has the ability to effectively monitor, analyze, and predict, much less control, society's multiscale, distributed, highly interactive networks.

Most complex systems and networks are expected to be robust and resilient in their daily functions. However, when stressed, they often respond in unpredictable and catastrophic ways, as in the following examples:

▷ *Physical Communications Networks*—current systems and networks cannot provide assurance of uninterrupted, secure, and fast electronic communications (cyber infrastructure, terabyte networks, security, interoperability, etc.);

▷ *Energy Distribution Networks*— the electric power grid is not currently capable of matching energy supply, demand, and distribution for all modes of use under real-time conditions;

- *Transportation Networks*—current networks do not prioritize efficient traffic flow, multimodal transports, minimal energy use, maximized public safety, maximized commerce, and social productivity; and

- *Biological Networks*—we do not have the ability to understand and control pervasive ad hoc networks within living systems and our environment.

The current technical and mathematical methodologies that underpin our ability to simulate and model physical systems are unable to sufficiently predict (much less control) the behavior of complex systems when they are stressed. In order to build knowledge and understanding and improve the ability to predict failure pathologies, the Nation will require the ability to accurately observe, analyze, learn, and predict the behaviors of complex systems under stress. Future R&D in this area could focus on the following objectives:

- Overcoming our limited understanding of current complex systems, as well as creating a paradigm shift in the Nation's ability to observe, understand, predict, and affect failure modes in complex systems.

- Developing observation and learning platforms for complex systems that enable a structured scientific approach to understanding and predicting failure pathologies within complex systems.

The Complex Networks team developed a white paper in 2010 that establishes a basis for future discussions concerning research directions with Federal agencies and other public and private entities.

Energy

TIP has identified energy as a critical national need area of interest and the smart grid as an important topic area. Although there is a general understanding of what components are required to achieve an active smart grid, there are key challenges essential to its full operation. These challenges include system-level modeling of highly variable systems (stochastic modeling), energy storage, the seamless integration of stored energy into the grid, advanced sensors with independent energy sources, system measurement, devices and methodologies for the wide-spread integration of grid-tied renewable energy sources, and high-voltage power electronics.

System-level stochastic modeling: Modeling for the grid has been deterministic, usually with the assumption that at most one major grid element will fail at any given time. However, introducing distributed energy storage and distributed renewable resources affects grid behavior in a complex manner better characterized by stochastic models.

Energy storage: Electrical storage for the smart grid integrates and addresses three requirements that involve diverse operational time scales:

- *Power quality:* response times of less than one-tenth of a cycle, ensuring continuity of quality power;

- *Bridging power:* response load support times of seconds to minutes ensuring continuity of service when switching from one source to another; and

- *Energy management:* response load support times of hours for decoupling the timing of generation and consumption.

Various systems to store energy are available today but have limited application to the grid system storage because of low-power limitations, low-energy density, or high cost. New technologies are needed to provide faster response times, increased reliability, improved benefit-cost ratios, higher capacities, and improved ability to integrate with high-voltage power electronics (that is, greater than 10,000 volts).

Advanced sensors: Grid security and monitoring systems will require multiple sensors distributed along transmission lines and along all significant grid components, including transformers, capacitors, switches, and breakers. These systems must provide data processing and communications capabilities operating independently of the grid power, while monitoring and reporting on the state of the grid in real time.

System measurement: Measurement needs for the smart grid fall into two categories:

- *Performance and efficiency:* New measurements will be needed to evaluate the state or condition of the grid. These will indicate the most efficient configuration of the grid and the most appropriate measurement to demonstrate that the grid has achieved a designated performance level.
- *Fine-scale measurements:* These measurements will accurately measure phase angle and frequency of the power on the grid over widely separated points. Subtle shifts in phase angle or frequency of power on the grid can lead to serious stresses and damage to major grid components. High-accuracy measurements of phase angle between distant points on the grid require sensors to be precisely synchronized.

Devices and methodologies for the widespread integration of grid-tied renewable energy sources: Widespread integration of renewables requires fundamental changes in the electrical systems design of the power grid. These changes will allow highly interactive generation and flow of power from thousands of relatively small sources and will be implemented by both new device designs and novel system topologies and algorithms. Some devices, such as inverters, have already been integrated into individual photovoltaic modules.

High-voltage power electronics (greater than 10 kilovolts [kV]): Power electronics is a key technology for interconnecting renewable energy generation to the grid, while providing ancillary services such as reactive power compensation, voltage and frequency regulation, and improved power quality and reliability. High-voltage power electronics (operating above 10 kV) employs switching devices to control and convert electrical power from one form to another, and is responsible for delivering electricity to the grid.

An updated version of TIP's draft white paper on this topic, entitled *Energy: Technologies To Enable a Smart Grid*, was made available for comment on TIP's website on October 28, 2010.[15]

Healthcare

Affordable and effective healthcare is important to the Nation's quality of life and central to its future growth. Yet escalating healthcare costs are a significant problem. Annual per capita healthcare spending in the United States is high and rising ($7,423 in 2007 and $7,681 in 2008)[16] and currently approved drugs do not always work for the entire population. Physicians typically lack the clinical information needed to select optimal drug treatments and dosages on the basis of a patient's unique genetics, physiology, and metabolic processes, which can result in trial and error in treatment.

[15] Available at http://www.nist.gov/tip/wp/upload/energy_wp_10_28_10.pdf

Significant advances have been made and large amounts of data generated through the pioneering Human Genome Project led by the National Institutes of Health (NIH) and the Department of Energy (DOE), and other Federal programs such as the "Tools for DNA Diagnostics" focused program funded by the former Advanced Technology Program at NIST. Accordingly, personalized medicine is attempting to unlock the important implications of genetic variability within the human organism to significantly alter approaches to new drug development, diagnostics, and treatment regimens in the 21st century and beyond. Although the advances in understanding genetic variability have raised high hopes for a new era in preventing and treating disease, major challenges remain in understanding complex biological systems in wellness and disease states. Understanding the connection between genetic and proteomic variations and disease states could provide earlier and more accurate diagnosis and targeted treatment.

Wellness and disease states also result from a complex interaction between an individual's genetic makeup and the influence of such environmental factors as diet, exercise, toxins, and drugs. With such Federal investments as described above, data resources such as genomic and proteomic databases and technologies are being developed to measure environmental toxins, dietary intake, and physical activity of individuals. To recommend preventive measures and safe and effective treatments, an integrated analysis of different data sets will be required. Such analysis may necessitate combining data from disparate sources, such as genomic, epigenomic, toxicogenomic, and proteomic databases, and linking it to patient-specific data such as nutrition, diet, and exercise, in order to lead to earlier and more accurate diagnosis and targeted treatment.

At this time, the manufacturing of biopharmaceuticals is complex and costly, and is based on a large-scale process involving batching and frequent sampling to monitor the quality and safety of production. Personalized medicine requires multiple smaller volumes of patient-specific biopharmaceuticals, and thus needs a change in the biomanufacturing model. Key enabling technologies are needed for automated high-throughput and cost-effective biomanufacturing that can simultaneously produce multiple safe, effective, and affordable patient-specific biopharmaceuticals.

TIP's proposed topic identified three challenges under the critical national need area of healthcare:

- Understanding of real-time protein interactions noninvasively in complex biological systems will enable real-time noninvasive tracking of cells and cellular molecules in living tissues and systems.
- Integrated analysis of multiple factors allowing linking of personal molecular biology to the environmental triggers necessitates combining data from disparate databases, such as genomic, epigenomic, toxicogenomic, and proteomic databases, and linking the data to patient-specific data, such as nutrition, diet, and exercise.
- Cost-effective manufacturing of diagnostic and therapeutic products is necessary for the success of personalized medicine.

An updated version of TIP's draft white paper on this topic, entitled Advanced Technologies for Proteomics, Data Integration and Analysis, and Biomanufacturing

[16] Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, "National Health Expenditure Da-ta," available at www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage.

for Personalized Medicine, was made available for comment on TIP's website on November 16, 2009.[17] Based on the public comments received, review of stakeholder meeting summaries on the web and discussions with the stakeholders by the TIP staff, and the gap analysis by the Science and Technology Policy Institute (STPI), biomanufacturing became a new topic in the 2010 TIP solicitation. Biomanufacturing here refers specifically to the manufacturing of biopharmaceuticals. Two types of biomanufacturing were considered: bioprocessing for production of biopharmaceuticals such as recombinant proteins as vaccines, therapeutics, or molecular probes for diagnostics; and advanced biofabrication and processing for production of cell or tissue-based biopharmaceuticals such as engineered cells and tissues as therapies. It is hoped that the results of the 2010 awardees in this area will enhance the field of personalized medicine and healthcare delivery in the United States.

Manufacturing—Advanced Robotics and Intelligent Automation[18]

Manufacturing is an area of critical importance to the Nation and its economy. Manufacturing represents the largest of the United States' private industry sectors, supporting more than 14 million jobs and accounting for almost 12 percent of gross domestic product (GDP) in 2007.[19] The societal challenge "Advanced Robotics and Intelligent Automation" within the critical national need area of Manufacturing has the potential to affect other important areas, including healthcare and homeland security. Input regarding potential societal challenges was obtained from Government agencies, scientific bodies (such as the National Research Council, National Academy of Sciences, and National Academy of Engineering), STPI, industry organizations, leading researchers from academic institutions, and others.

The U.S. manufacturing sector faces enormous challenges from a global economy. Long runs and large-volume manufacturers in such areas as automotive, semiconductors, and appliances have benefited from robotics and intelligent automation to increase productivity, quality, and economies of scale. However, these advantages have been slow to trickle down to small and medium manufacturers owing to such factors as high overhead costs, complexity of setups, and insufficient flexibility and agility. It is particularly difficult for small and medium manufacturers to develop these capabilities because the robotics industry is in its infancy and fragmented, and each new application-specific solution restarts the design process.

Talks with individual leaders in the robotics community identified the need to support infrastructural technologies as a high priority. For these technologies to advance, high-risk, high-reward research and development will be needed in areas like the following:

- ▷ Dexterous manipulation (the ability to grasp and operate on arbitrary objects);
- ▷ Concurrency (parallel activities, networking, and cross-communications);
- ▷ Navigation and 3-D planning (autonomous movement without collisions);

[17] Available at http://www.nist.gov/tip/wp/upload/healthcare_wp_11_16_10.pdf

[18] For this discussion, robotics and automation are defined by the Institute of Electrical and Electronics Engineers' Robotics and Automation Society: Robotics includes intelligent machines and systems used, for example, in space exploration, human services, or manufacturing; automation includes the use of automated methods in various applications (e.g., factory, office, home, laboratory automation, and transportation systems) to improve performance and productivity. More information is available at http://www.ieee-ras.org

[19] Statistical Abstract of the United States, 2009, Table 964, http://www.census.gov/prod/2008pubs/09statab/manufact.pdf

- Power and energy systems (the ability to work for 8-plus hours without a power cord or tether);
- Safety and human-robot interaction (the ability to work alongside people without risk);
- Wireless communications (the ability to communicate with autonomous robots in a noisy electromagnetic environment); and
- Cooperation between different system components (integration that is easy and flexible).

TIP's draft white paper on this topic, entitled *Manufacturing: Advanced Robotics and Intelligent Automation*, was made available for comment on TIP's website on November 16, 2010.[20]

Sustainability

According to a widely used definition, sustainability entails "meeting the needs of the present generation without compromising the ability of future generations to meet their needs."[21]

Sustainability is a complex and highly interdisciplinary endeavor with economic, environmental, and societal dimensions. The opportunity for TIP is to assist in developing technologies that reduce or eliminate the environmental footprint of industrial processes and public waste:

- Current domestic consumption of materials and chemicals produces large amounts of waste and is based on finite resources, and many of these materials, critical to our economy, must be obtained from countries that pose geopolitical concerns. For example, although industry has made tremendous strides in transitioning to cleaner, safer chemicals (such as phasing out chlorofluorocarbons, or CFCs), in 2008 almost 4 billion pounds of toxic materials were disposed of or released into the environment in the United States.[22]
- In 2008, the United States emitted more than 7 billion metric tons of carbon dioxide, a greenhouse gas of much social concern.[23]
- Every year, 25,000 pounds of new, nonfuel minerals must be provided for every person in the United States.[24]

With the assistance of Government agencies and nationally recognized scientific organizations (such as the National Research Council, National Academy of Sciences, and National Academy of Engineering), STPI, industry organizations, leading researchers from academic institutions, and others, TIP identified some of the societal challenges associated with addressing the critical national need of sustainability:

- *Chemicals Production through Metabolic Engineering*—To develop bio-based process technologies that reduce the consumption of petroleum resources; reduce waste byproducts, including emissions; and provide safer pathways for producing high-value-added chemicals.
- *Critical Minerals Availability*—To develop new technologies that improve domestic capabilities to

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[20] Available at http://www.nist.gov/tip/wp/upload/robotics_wp_11_16_10.pdf.

[21] United Nations, *Report of the World Commission on Environment and Development: Our Common Future*, available at http://www.un-documents.net/wced-ocf.htm.

[22] U.S. Environmental Protection Agency, *Toxics Release Inventory Reporting Year 2008 National Analysis: Summary of Key Findings*, available at http://www.epa.gov/TRI/tridata/tri08/national_analysis/pdr/TRI_key_findings_2008.pdf.

[23] U.S. Department of Energy, Energy Information Administration, *Emissions of Greenhouse Gases in the United States 2008*, available at ftp://ftp.eia.doe.gov/pub/oiaf/1605/cdrom/pdf/ggrpt/057308.pdf.

[24] National Research Council, *Minerals, Critical Minerals and the U.S. Economy*, 2008.

recover, recycle, and provide substitutes for limited-resource materials such as platinum metals, rare earth elements, indium, and manganese.

Water

Everyone needs clean water for all phases of daily life. Thus, the need for advanced technologies for better managing water quality is both national and critical. Water supply is a complicated matter. The quantity of freshwater at any particular location and time depends on climate and the movement of water through the hydrosphere. The desired outcome is to improve means for managing the quality and quantity of supplies of delivered water and to protect the public from waterborne diseases.

Current sensing technologies for detecting and identifying pathogenic and chemical toxins, although well developed in controlled laboratory environments, have not yielded tools for producing real-time, in situ data for routine use in the food distribution chain or for multiple-site deployment in municipal water systems. Environmental issues related to the discharge of concentrated brine from reverse osmosis plants limit deployment, as permitting is a major constituent of the fixed costs of current desalination projects. The energy costs of new means to produce water and treat wastewater need to be reduced to decouple water prices from energy prices and availability. Just as energy prices enter into national economic pressures, so too will water prices as security and scarcity affect the cost of delivered water. The following societal challenges are critical to maintaining the water supply necessary for the Nation:

- *Water Quality*—Disinfection and Decontamination: Disinfection and decontamination of water before distribution are essential to meet current and future standards of water quality. As the list of regulated substances grows, and as regulated contaminant levels drop, current disinfection and decontamination technologies face serious challenges and will require significant technical advances to meet future needs.
- *Water Quantity*—Reclaimed Water and Desalination: As water demand grows and as regions undergo long-term climate changes, societal challenges to supplement freshwater sources are increasing. At least three means are related to relieving pressure on local water supplies: conservation, reclamation of wastewater, and desalination of brackish water or seawater. The high cost of water reclamation currently prohibits widespread use to supplement domestic water supplies.[25] The economics of water reclamation depend not only on the water purification technology but also on disposition of the residual material left after water removal. Because reclamation of wastewater and conservation both depend on an initial supply of water, which may decline or disappear for some communities, desalination of brackish water or seawater must also be considered for communities whose future needs for water are projected to exceed available freshwater supplies. Significant technical barriers to desalination include the uncertain environmental impacts of the resulting concentrated brines and the potential for aquatic biota to be harmed by water intakes.
- *Resource Recovery from Wastewater:* Municipal wastewater streams contain significant unrecovered energy and chemical resources. New technologies are needed to cost-effectively derive energy from waste biosolids, such as

[25] National Institute of Standards and Technology, *An Assessment of the United States Measurement System: Addressing Measurement Barriers To Accelerate Innovation* (NIST Special Publication 1048), available at http://usms.nist.gov/files/USMS-Assessment-Report-2006.pdf

hydrogen, natural gas, or other energy carrier. Better technologies are needed for recovering phosphorous from both the discharged water and the solids portion of the waste stream. A particular challenge for phosphorous recycling technologies is the removal of heavy metals from the produced phosphorous product. Ultimately, municipal waste could become an economic resource.

TIP's draft white paper on this topic, entitled *Water: New Technologies for Managing and Ensuring Future Water Availability*, was made available for comment on TIP's website on November 16, 2010.[26]

[26] Available at http://www.nist.gov/tip/wp/upload/water_wp_10_28_10.pdf.

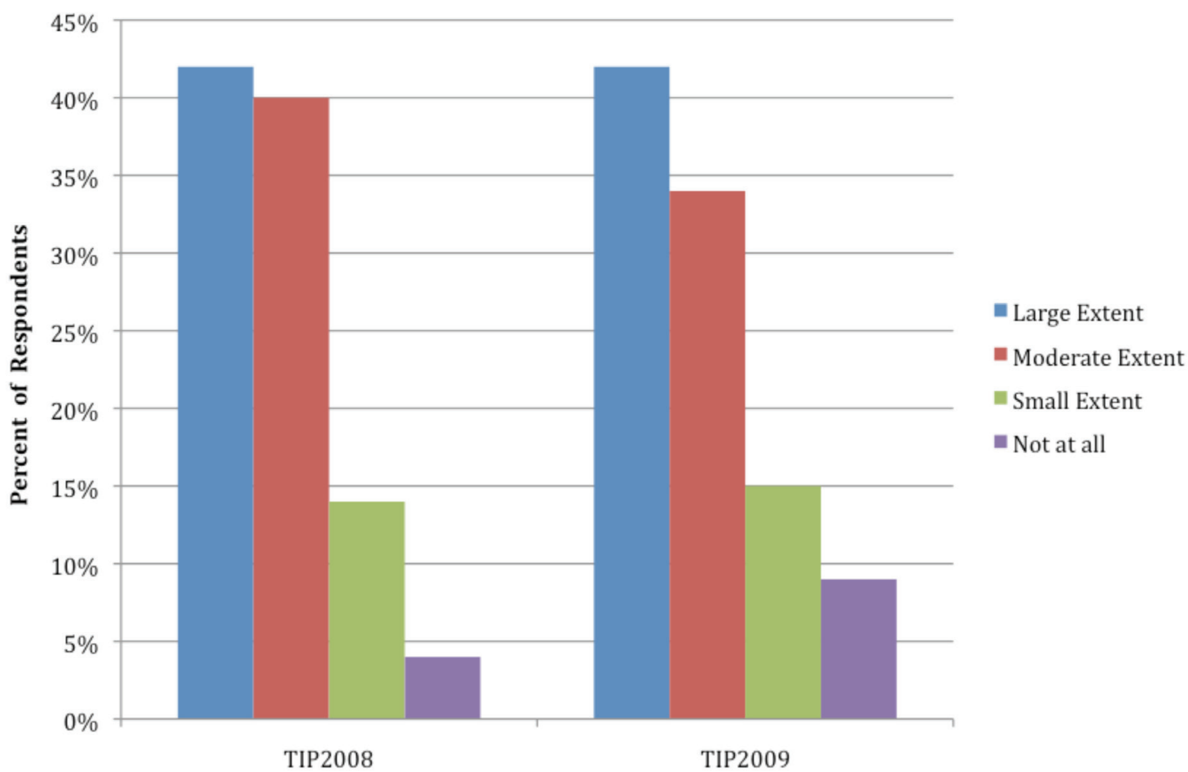
SECTION 4▶

Findings from TIP's Impact Analysis Office

Findings from the Customer Satisfaction and Applicant Surveys of the 2009 Competitions

In July 2010, TIP surveyed single company leads and joint venture members, who had submitted proposals to the 2009 TIP solicitation in Civil Infrastructure and Manufacturing. The response rate was 57 percent for the 206 potential respondents. Preliminary analysis suggested that the nonresponse rate did not exhibit a systematic bias for demographic characteristics, such as company size or if the proposer was part of a single company proposal or a joint venture member, which means that the survey responses likely reflect an accurate sample of the overall population of applicants. TIP conducted a similar survey for the 2008 solicitation in Civil Infrastructure. The program fielded the surveys in the year following these competitions. The rationale for this timing, in part, is that TIP is interested in examining the counterfactual evidence that programmatic funding has made a difference. After a year, TIP can discern the extent to which proposed research that did not receive TIP funding has been pursued and if any results have occurred from these efforts. TIP can then compare

Figure 1: Applicant Perceptions Regarding the Fairness of TIP's Review and Decision Process

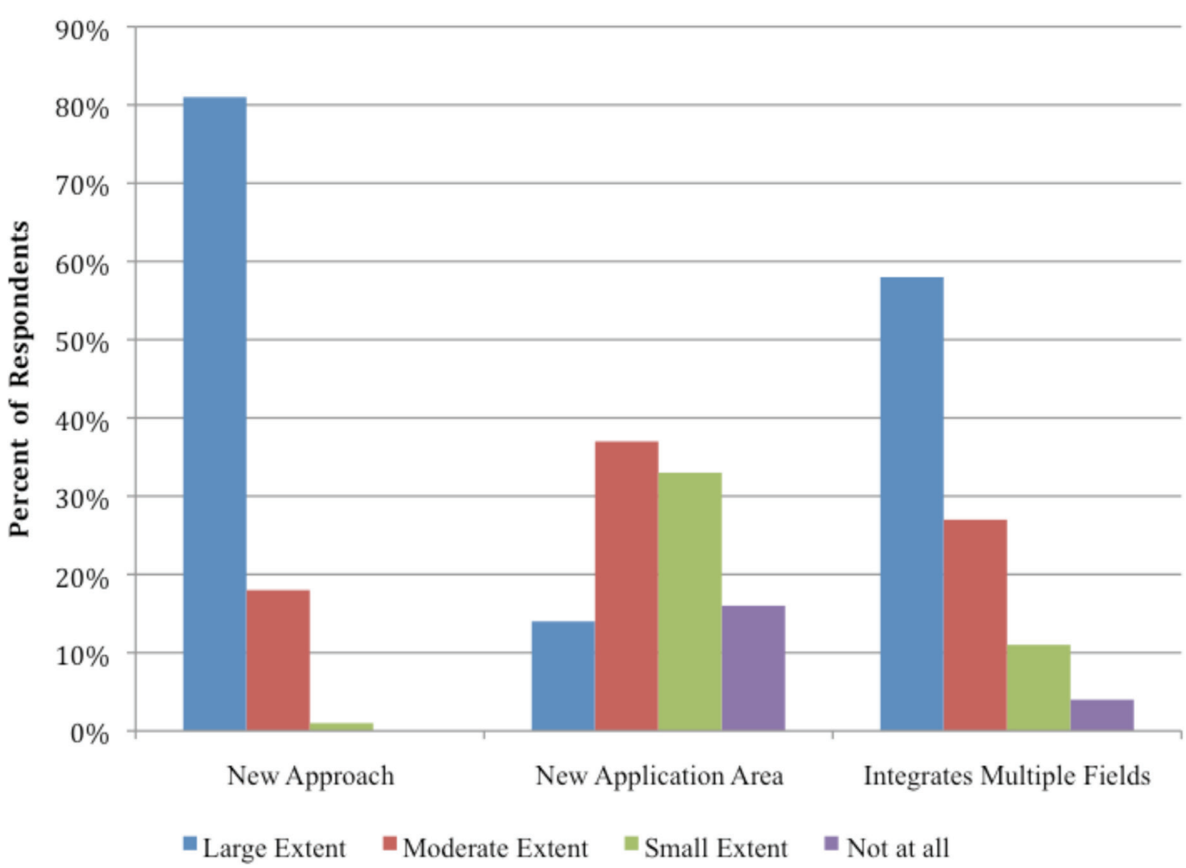


these efforts with the projects receiving funds in order to assess the impact of programmatic funding. The survey also contained questions surrounding the specifics of the proposed research. The applicant survey helped TIP assess the extent to which it is meeting its statutory mandate. A final component of the survey was a series of customer satisfaction questions assessing proposer interaction with TIP. TIP actively pursues stakeholder feedback regarding the effectiveness of its resources for proposers, the value of interaction with TIP staff, and whether the selection process was perceived as fair regardless of the funding decision.

Customer Satisfaction

TIP's staff work hard to keep peer-review selection fair and focused on the criteria. Proposers should be able to view the process as fair regardless of whether they ultimately received an award from TIP. The applicant surveys asked all applicants (awardee and nonawardee alike) the following question: "To what extent do you believe the TIP review and decision process was a fair process?" Figure 1 shows that for the first two competition years, most respondents viewed the TIP selection process as fair.

Figure 2: How Does TIP "Stretch" Its Applicants?



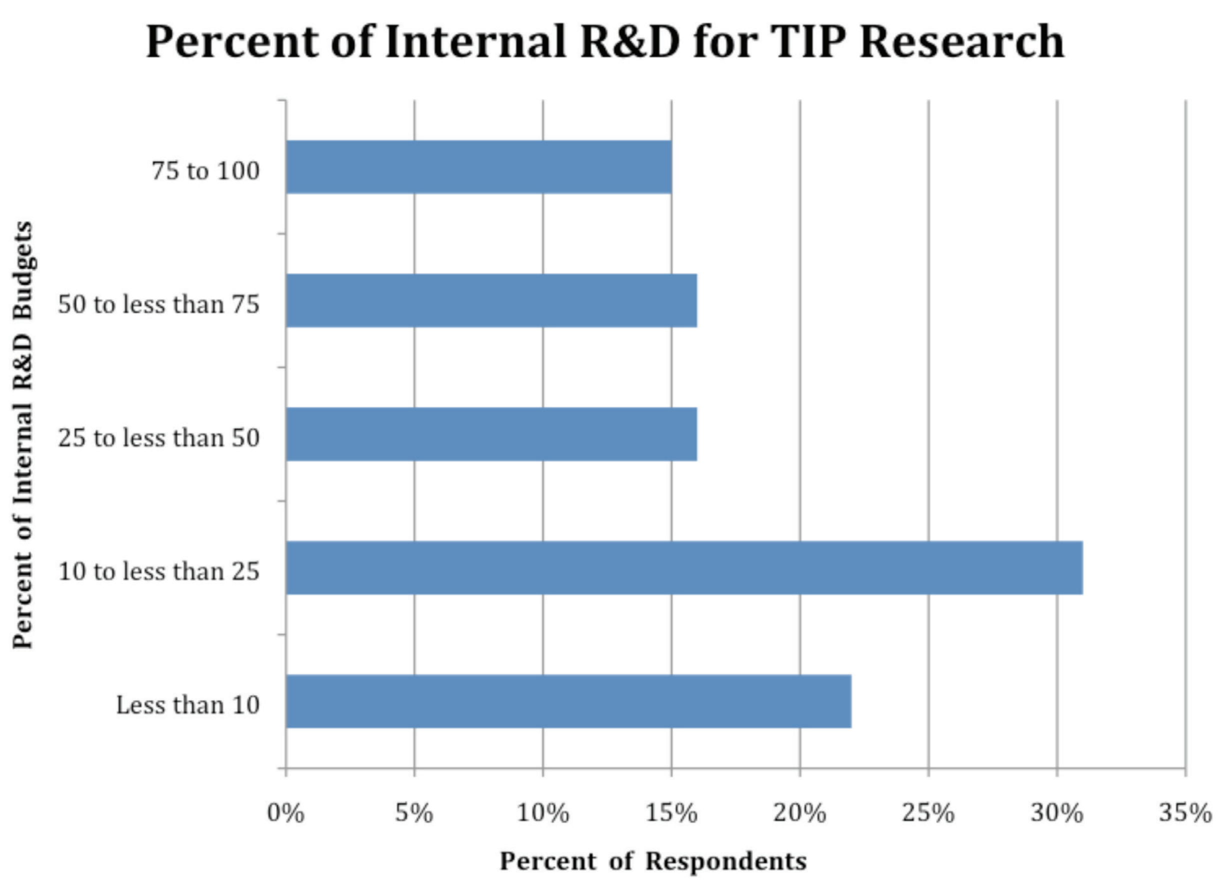
Stretching Research and Development

Part of TIP's mission of funding cutting-edge research involves cost-sharing with small and medium businesses, universities, and other organizations to help them stretch their R&D efforts. The applicant surveys explored three ways that TIP proposals represented stretching all applicants (awardee and nonawardee) in research approaches beyond what they normally do. These included applying a new technical approach to a problem, applying research findings to a new scientific area, and integrating multiple fields of study. Figure 2 shows that TIP-proposed research not only helps organizations to develop new scientific approaches, but also expands their horizons in new applications of science and collaborations across related technical disciplines.

TIP Is Not Replicating or Replacing Existing R&D Expenditures

One of TIP's award criteria is that "no other alternative funding sources are reasonably available to support the proposal." TIP asked respondents to think about the line of research that was proposed to TIP and to report what portion of their previous internal R&D was associated with the proposed TIP technologies. Figure 3 shows that nearly 70 percent of respondents

Figure 3: TIP Does Not Replace Core R&D Expenditures



indicated that the technical work proposed to TIP represents less than half of their internal R&D efforts, indicating that internal R&D funding is not being used to fund the TIP proposed efforts.

In the Absence of TIP Support, Proposed Research Is Not Pursued

Part of TIP's mission is to fund projects that would not have been pursued in the absence of Government support. TIP awardees have demonstrated that the proposed R&D would not have occurred without this private-public partnership. TIP asked nonawardees the extent to which they were pursuing the proposed TIP research tasks a year after their proposal was not funded. Among these nonawardees, there is strong support that TIP is attracting the types of proposals that represent efforts that businesses would not pursue in the absence of TIP support. Survey results indicated that more than a third of organizations (37%) were not pursuing any of the proposed TIP R&D tasks. Those organizations continuing to explore research proposed to TIP only partially explored the research tasks proposed to TIP. An additional 40 percent of responding organizations indicated that they were pursuing less that 20 percent of the research agenda proposed to TIP.

APPENDIX ▶

Abstracts of the 2010 TIP Awards

Volume Production of Nanocomposite Alloy Anode Materials for Lithium-Ion Batteries

ActaCell, Inc. (Austin, TX)

Project Duration: Three Years
Projected TIP Contribution: $3,000 K
Total Project Cost (est.): $6,197 K

ActaCell, Inc., a start-up company based in Austin, Texas, plans to develop technology necessary to scale-up production of the company's novel nanocomposite material for high-performance lithium batteries by a factor of a thousand, potentially enabling safe, powerful and economical batteries for electric vehicles and other demanding applications. Lithium-ion batteries could be an excellent choice for large energy storage applications such as plug-in hybrid (PHEV) and electric vehicles (EV), because they can store far more energy in a smaller space than other types of batteries—which translates to lighter, more efficient vehicles with greater range. However, lithium batteries face several technical challenges, principally related to achieving a high level of safety while maintaining a low cost. One of the primary safety issues in current lithium-ion batteries is related to the use of graphite as the battery's anode and the electrochemical interaction between the graphite anode and the electrolyte. ActaCell has developed a novel nanocomposite anode material, based on research at the University of Texas at Austin, which greatly reduces the reactivity of the anode under abusive conditions. The ActaCell anode material also is, in principle, significantly less expensive to produce. To be commercially viable, ActaCell must be able to scale-up the production of its nanocomposite anode material from the current laboratory batches of about 5 grams to 5 kilograms economically. To achieve this, the company proposes to use a technique called Reactive High Energy Milling (RHEM) that drives a chemical reaction via the use of a high energy reactive milling in one single reaction scheme. Commercial scale use of RHEM is untried in the lithium battery industry, and is complicated by a number of process variables that are not expected to scale uniformly, but is critical to keep the processing and overall materials cost low. The scale-up of this synthesis process will be a key innovation not only in the lithium-ion battery industry, but also as a low-cost manufacturing technique for other related materials. These combined innovations are key to advancing adoption of large-scale energy storage, offering potential transformation of both the automotive and electric utility sectors.

Critical Process Advance to Transform Production Rates of Core-sheath Electrospun Fibers Enables Manufacturing of Micro- and Nanofibrous Devices in Practical Commercial Volumes

Arsenal Medical, Inc. (Watertown, MA)

Project Duration: Three Years
Projected TIP Contribution: $2,279 K
Total Projected Cost (est.): $4,706 K

Good things often come in small packages—like the ultrathin core-sheath fibers now being eyed for applications ranging from controlled drug delivery systems and tissue regeneration to self-healing coatings and self-cleaning filters. Core-sheath fibers are fibers with a concentric structure, one material surrounding another. (Think of an insulated copper wire, but much smaller.) Arsenal Medical intends to develop a high-throughput, core-sheath electrospinning technology that greatly increases the rate of producing these slender cylindrical packages. The anticipated jump in processing speed would move promising—but unaffordable—prospective products requiring high-throughput manufacture of core-sheath fibers into the realm of the commercially viable. Ranging in diameter from about 100 nanometers to 20 micrometers, core-sheath fibers are among the most promising members of a growing family of electrospun materials. In electrospinning, a high-voltage electrical field is used to charge and stretch a droplet of a polymeric solution while on its way to a grounded collector plate or screen. Depending on the composition of the starting materials, operating conditions, and other factors, the process outputs can take the form of a range of shapes and textures including meshes, tubes, or structures that look like yarns. A major challenge is to develop methods that yield fibers of uniform quality in volumes sufficient for commercial production. This is especially true for core-sheath fibers because of their concentric design, which encapsulates one material within another. Production yields with the current state-of-the-art method—a pump-driven needle with low flow rates—are a fraction of a gram per hour, according to Arsenal Medical. Extending a newly introduced technology, the company will leverage the physics of electrospinning to devise a process that generates multiple fiber-forming jets composed of two materials in the desired arrangement. In addition to revving up production rates by more than 500-fold, the nascent process does not require multiple nozzles, as would an alternative option. Arsenal Medical says its approach can overcome logistical, quality-control, and cost issues that impede other approaches to scaling up production of core-sheath fibers for marketplace applications.

Atmospheric Spray Freeze Dried Powder Process Advancement and Scale-Up

Engineered BioPharmaceuticals, Inc (Manchester, CT)

Project Duration: Three Years

Projected TIP Contribution: $2,988 K
Total Projected Cost (est.): $5,977 K

Engineered BioPharmaceuticals, Inc., a small start-up company, plans to scale-up and demonstrate a commercially viable process for freeze drying protein-based pharmaceuticals in aseptic, powder forms. If successful, the company's technology could significantly simplify the use of emerging, protein-based therapies by stabilizing the drugs, extending their shelf life, and making them amenable to a variety of simple, reliable delivery mechanisms such as low cost inhalers and point-of-use devices. Advances in biotechnology have opened up a new class of pharmaceuticals based on engineered proteins that can selectively target specific disease mechanisms with relatively few side-effects. The field, still in its infancy, has great potential to prevent or combat many diseases and provide an arsenal of therapies to counteract pandemic and bioterrorism agents. Biomolecular-based drugs, however, are large and complicated molecules that must be handled carefully to preserve their effectiveness. They generally cannot be delivered as pills or otherwise ingested because the digestive mechanism is specifically designed to break down proteins. Currently, most are injected as liquids by a less than enthusiastic patient-base. Due to the relatively short shelf life stability of liquid biomolecular-based drugs, they often require special handling, such as maintaining cold chain storage and/or clinician administration, both adding to increased cost and limiting distribution. Establishing a long shelf life through aseptic processing into dry powders is a cost effective and essential process for efficient storage of stockpiles required for epidemics and pandemics. Engineered BioPharmaceuticals has pioneered an atmospheric spray freeze drying (ASFD) process to create high performance dry powders in controlled sizes for biomolecular pharmaceuticals. Freeze drying has been used to preserve things such as blood serum since World War II, but existing commercial processes produce either solid cakes or poorly defined powders that are unsuitable for aerosol delivery and can be difficult to dissolve while maintaining therapeutic value. The project entails significant technical challenges in creating a hybrid manufacturing process that combines the characteristics of spray drying and freeze drying while maintaining a fine control over particle shape. Technical barriers to be overcome include preventing stresses on the biomolecules that damage their therapeutic value; handling aerosol distributions with particle dimensions ranging from the micron scale to the sub-micron scale without loss of expensive product (much like catching smoke and placing it in a small bottle without losing any); and performing all operations in aseptic environments. The company proposes to build and demonstrate an integrated production line capable of manufacturing aseptic dry powders and filling them aseptically into delivery devices. A non-pharmaceutical test material will be used to demonstrate the production and packaging of aseptic powder batches at a variety of size scales, including nanoscale particles, and particles suitable for pulmonary delivery, nasal delivery, and reconstitution. The company also will produce a recombinant protective antigen vaccine powder to demonstrate the process' potential with actual proteins.

Volatile Reporters for Biomanufacturing of Protein Therapeutics

Ginkgo BioWorks, Inc. (Boston, MA)

Project Duration: Two Years
Projected TIP Contribution: $1,000 K
Total Project Cost (est.): $2,300 K

Ginkgo BioWorks aims to develop genetically-engineered tools for in-line, real-time monitoring of the fermentation processes used in the production of pharmaceutical proteins. The company's novel "reporter technology," intended for integration and use with analytic equipment already in place in biomanufacturing operations, will facilitate the monitoring, control, and optimization of fermentation processes used to produce monoclonal antibodies, vaccines, and other biologic compounds for medical and industrial applications. Made in cells, biologics constitute one of the fastest growing segments of the pharmaceutical industry. Yet, determining and maintaining fermentation process conditions that yield acceptable levels of these compounds can be exceedingly challenging. Slight variations in process conditions can stress cells, suppress expression of genes that code for desired proteins, or interfere with the folding and post-translational modification of proteins as they are being assembled inside cells. Existing process-monitoring methods only make periodic measurements of many sample variables—akin to taking multiple photographs. With the tools of synthetic biology, Ginkgo BioWorks proposes to fashion the biomanufacturing equivalent of real-time video monitoring. By inserting so-called reporter genes at strategically located sites in the production cell's genome (the cell's hereditary information), the company will create the means to continuously track the health of cells and the growth conditions in fermentors. Changes will trigger the reporter genes to initiate production of volatile reporter compounds that can be detected with gas chromatography-mass spectrometry instruments, which are standard in biomanufacturing. With this capability, manufacturers could make real-time adjustments to maintain optimal production conditions. In-line monitoring would also simplify steps required to demonstrate conformance with regulatory requirements, thereby facilitating further innovation in manufacturing practices.

Production of Fully Deleted Helper-Virus Independent Adenoviral Vectors

Isogenis, Inc. (Aurora, CO)

Project Duration: Three Years
Projected TIP Contribution: $2,756 K
Total Project Cost (est.): $5,511 K

Since viruses are designed by nature to transport genetic material into an infected host cell, biotechnology researchers have developed various ways to adapt viruses as vectors to transfer genes for therapeutic purposes. Isogenis, Inc. has developed a versatile gene transfer vector based on the adenovirus, a family of common viruses. In this project Isogenis hopes to develop improved manufacturing technologies for commercial-scale production of modified versions of their adenovirus (Ad) vector, intended for a variety of medical uses, including vaccines, organ and tissue transplants, and gene therapy. The Isogenis Ad vector is fully deleted, meaning that it is essentially an empty icosahedral shell stripped of all the original virus genes. It is believed to be highly safe; it is not infectious and does not integrate into the target cell chromosomes. Isogenis is exploring the use of the Ad vector to create safe vaccines that can be developed rapidly for diseases ranging from influenza to dengue hemorrhagic fever. It also could be used to protect transplanted tissue from body's immune system without the need for immune suppression drugs, and as a gene therapy vehicle to treat diseases such as hemophilia and cystic fibrosis. Producing Isogenis's Ad vector is complicated because the deletion of all the Ad genes means that the biochemical information needed to assemble the vector, together with its biopharmaceutical payload, must be provided separately. Other helper viruses could be enlisted to do this, but the Food and Drug Administration has expressed concerns that this runs the risk of contaminating the final product. With TIP support, the company plans to develop and optimize standardized manufacturing systems for fully deleted, helper virus-independent Ad (fdhiAd) vectors that would enable mid- and large-sized batch manufacture of pharmaceutical-grade vectors for vaccination, gene therapy and tissue transplantation applications. If successful, the technology would provide valuable new capabilities to the nation's healthcare system. The vaccine applications alone would be important in combating emerging infectious threats and bioterrorism because the fdhiAd-based vaccines could be developed more quickly and at lower cost than traditional vaccines.

Process Innovation for High Technology Manufacturing of Flexible Liquid Crystal Displays

Kent Displays, Inc. (Kent, OH)

Project Duration: Three Years
Projected TIP Contribution: $2,996 K
Total Project Cost (est.): $6,005 K

With the vast majority of liquid crystal displays (LCDs) now manufactured in Asia, Kent Displays proposes to develop a suite of processes for high-volume production of flexible, low-power displays—an emerging technology that can help U.S. businesses establish a solid foothold in the growing flat-panel market, now totaling about $150 billion globally. If successful, the project will result in the first U.S. facility for commercial scale manufacturing of high-resolution digital displays of any type. The displays will be made from thin flexible, plastic films, as opposed to the thin-film transistor LCDs made of breakable glass. Used in flat screen TVs, laptop computers, cell phones, and other devices, these glass LCDs account for most of the global market. Rather than challenge the entrenched technology, Kent Displays plans to open new markets by introducing its low-power, high-resolution Reflex™ displays for use on credit cards; as electronic paper for broad-scale applications, such as advertising; in low-cost writing tablets, and for other mass-market offerings. Because they reflect ambient light, Reflex displays do not require backlighting; nor do they require constant refreshing. Both attributes greatly reduce power consumption. The company recently progressed from batch processing to continuous roll-to-roll manufacturing of Reflex flexible displays, enabling it to produce a first-generation electronic writing tablet in volume for the mass market—the popular Boogie Board™ LCD Writing Tablet. Now it aims to increase production capabilities and lower costs for Reflex flexible displays by developing seven new manufacturing processes. These processes are expected to provide the framework for attaining the high-yield, high-volume production capacity necessary to expand markets for the Boogie Board tablet as well as capture markets for new LCD products that exploit the attributes of Kent Display's flexible technology, including low power, low cost, and high resolution. Kent Displays will maximize the effectiveness of the processes by integrating them into an on-line system where each process rests on the capabilities of the others. Collaborators contributing to the project include the University of Akron and the Manufacturing and Growth Network (MAGNET), as well as a host of other close partners and strategic suppliers.

Novel Nanomaterial Synthesis Processes to Enable Large-Scale, High-Performance, Flexible Solar Module Manufacturing in the United States

Polyera Corporation (Skokie, IL)

Project Duration: Two Years
Projected TIP Contribution: $2,051 K
Total Project Cost (est.): $4,953 K

Thin-film organic photovoltaic (OPV) materials have the potential to bring the promise of low-cost, ubiquitous solar power to fruition while reinvigorating U.S.-based manufacturing and construction. Polyera has developed a class of semiconductor materials with the potential to reach ten percent power-conversation efficiencies (PCEs), the level needed to enable solar modules competitive with other technologies on a cost-per-watt basis. It proposes to develop cost-effective, high-yield synthetic methods to enable the large-scale manufacturing of these materials. The project will develop and evaluate novel synthetic routes for making the fundamental building block. It also will examine the potential of a highly-novel polymerization method—never before used in the industry—to better control the photoactive layer polymer architecture at the nanoscale. Compared with traditional polymerization methods, this new approach offers the advantages of reduced complexity and greater control over molecular weight and polydispersity, ultimately leading to higher-yield, lower-cost, and higher-performance polymer production, thus optimizing device performance. Polyera will work with third parties to scale-up the process first to pilot levels and then to commercial scale volumes, while ensuring that the material performs adequately and is suitable for solar modules. Having reliable, cost-effective production of high-efficiency, easy-to-process photoactive materials would drive down solar module manufacturing and installation costs, create new sectors for U.S. manufacturing in a market with global demand, and provide cost-effective, renewable energy on a much larger scale.

Genetic Engineering of Elite Bioproduction Cell Lines

Precision BioSciences, Inc. (Research Triangle Park, NC)

Project Duration: Three Years
Projected TIP Contribution: $2,712 K
Total Project Cost (est.): $5,453 K

Precision BioSciences aims to develop a genomic engineering tool kit for reprogramming a key biological process that largely determines the yield, quality, safety, and cost of monoclonal antibodies and other therapeutic proteins produced with Chinese hamster ovary (CHO) cells. The industry standard cell line, CHO cells are used to make about two-thirds of all glycosylated biopharmaceuticals, which in turn account for about a quarter of all new drugs approved for clinical use. The complex process—known as glycosylation—involves dozens of enzymes and other biomolecules. These enzymes are engaged in linking sugar molecules (saccharides) to various amino acids that make up a protein. The final arrangement of sugars affects the properties of the resultant glycoprotein, including its safety, effectiveness, availability, and longevity in the body. Because of challenges in optimizing glycosylation, production of glycoproteins is time-consuming and costly. Achieving precise control of the process in CHO cells would make it far easier to optimize therapeutic proteins so that dosage requirements for some biopharmaceuticals now in the markets could be reduced by as much as 80 percent, according to Precision BioSciences. Using its technology for cleaving strands of DNA at specific points and inserting new genetic instructions, the company will edit and reprogram multiple genes in a single CHO cell and modify reaction pathways involved in glycosylation to target specific sugars. The novelty and challenge of the project lie in its scope and in manipulating multiple genes in the same CHO cell line without negatively affecting its growth or capacity to produce biopharmaceuticals. Because it is difficult to manipulate the genomes of living mammalian cells, previous attempts to modify glycosylation have been limited to a single gene. In this TIP project, Precision BioSciences aims to optimize a large ensemble of genes and their products. Because CHO cells already are integral to a large segment of the biomanufacturing industry, implementation of process technologies resulting from the project would not require a major overhaul of the industry's existing infrastructure. More efficient processes also would help to foster the emergence of a competitive generics market for biopharmaceuticals. Knowledge gained in this project is expected to advance the state of the art in genomic engineering and synthetic biology.

Low Cost, Scalable Manufacturing of Surface-Engineered Super-Hard (SESH) Substrates for Next Generation Electronic and Photonic Devices

Sinmat Inc. (Gainesville, FL)

Project Duration: Three Years
Projected TIP Contribution: $2,398 K
Total Project Cost (est.): $4,801 K

Sinmat is pursuing a practical, cost-effective solution to a hard technological problem impeding progress toward next-generation integrated circuits, advanced power electronic devices, and enhanced solid-state-lighting technology. The company plans to develop commercial-scale methods for making super-hard, low-defect substrate materials and engineering the surfaces of these advanced technology platforms to eliminate roughness and optimize properties for particular applications. Success could pave the way for silicon-on-diamond (SOD) substrates to meet the need to rapidly dissipate heat on future generation integrated circuits. By 2016, according to the semiconductor industry's technology roadmap, the thermal properties of the current substrate material—silicon on insulator—will fall short of what is needed. However, SOD technology is not ready to fill the void because methods currently available cannot smooth diamond surfaces to the required level—less than 1 nanometer in variation. Near perfect surfaces on super hard substrates also are required for improving brightness of light emitting diodes, eliminating defects that impede the performance of high-power devices, and creating large sheets of graphene of the desired thickness to enable commercial applications of this promising, but still experimental nanoscale material. Sinmat's surface-engineered super-hard substrates are designed to greatly reduce surface roughness, reduce defect density, and enhance light reflection. The company proposes to refine and scale-up its state-of-the-art chemical mechanical polishing techniques for engineering the surfaces of gallium nitride, silicon carbide, diamond, and other extremely hard materials. This capability could spawn an estimated $1 billion market for super-hard materials with engineered surfaces, enhance energy efficiency in lighting and other products, and reduce manufacturing costs in the semiconductor industry.

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