



February 2006 SBIR Newsletter Material

Events to be included in “Events” link:

Innovators Network: “From IP to VC - Turning your Innovations Into a Successful Business”
February 7th from 11:30 – 1:30, The Solution Center - Wilmington Room, 1101 Slater Road
Durham, NC <http://actonline.ga4.org/sign-up-for-our-nc.html>

UNC – Office of Tech Development Seminar: "How are the patent rules changing?"
February 9, 2006 from 5:15 to 6:15 pm in 014 Sitterson Hall
<http://research.unc.edu/otd/seminar>

Combination Medical Device / Biotech Forum – February 13, 2006, NC Biotech Center
https://secure.cednc.org/programs/industry_forums/biotech_forum/register.htmls

Tri-State SBIR Forum – March 21-23, Roanoke, VA

Agenda: http://www.sbtdc.org/technology/Agenda_Roanoke.pdf.

NC attendees can register by contacting John Ujvari (phone: 919-962-8297 or by email:
sbir@sbtdc.org)

SBIR Seminar – April (Date TBA), NC A&T State University. Featuring NASA and NIH
Registration and agenda available at <http://www.sbtdc.org/events/sbir/workshops2006>

SBIR Seminar – April (Date TBA), UNC – Chapel Hill. Featuring NIH
Registration and agenda available at <http://www.sbtdc.org/events/sbir/workshops2006>

MBA Summer Consulting Program Invitation Opens

The SBTDC acts as a liaison between small RTP-based tech firms and several MBA programs in North Carolina, including the Kenan-Flagler School of Business at UNC-Chapel Hill, the Babcock Graduate School of Management at Wake Forest University and the Fuqua School of Business at Duke University. Each summer we match MBA interns (MBA students who have completed their first year of business school) with high potential small tech firms that have defined a clear project to which the intern will be assigned. Interns generally work with two firms during the 10-week internship, 2.5 days per week with each. Since the program's inception, over thirty RTP firms have leveraged thousands of hours of assistance through the SBTDC's MBA intern program.

If you are interested in participating in this year's program please contact John Ujvari for application materials.

NC IDEA Grant Program Opens

NC IDEA, a private non-profit organization dedicated to helping establish and develop early-stage companies through commercialization of research innovation, is launching the **NC IDEA Grants Program** beginning January 15 to help companies bridge the gap between idea and private equity funding. For more information or to apply for a grant, please visit the NC IDEA Web site (<http://www.ncidea.org/grantsandloans.html>.)

NC IDEA plans to award \$150,000 in "proof of concept" grants in April 2006, with a maximum of \$50,000 per company. North Carolina-based companies focused on information technology, medical devices or material sciences are invited to apply, with preference given to those that have not received equity financing. An entrepreneur who has not formed a company may apply, but company incorporation will be required prior to the award of grant funding. The grant cycle will begin Sunday, Jan. 15. Interested companies are invited to submit an online "pre-proposal" application through Feb. 15.

The NC IDEA Grant Program is a catalyst that will ultimately produce high-growth companies and jobs in North Carolina by helping position companies for private equity investment.

NC IDEA Grants will support business activities such as development of a business plan, market research and analysis, IP activities or prototype development. Grants will not be awarded to fund scientific research or pay salaries.

Approximately a dozen companies submitting "pre-proposal" submissions will be selected to participate in a subsequent full proposal submission and review period from Feb. 15 through March 22. This process will include submission of a more in-depth proposal and budget for use of grant proceeds, and potentially a presentation from the company to a NC IDEA Grants Program advisory committee. Notification of grant recipients is scheduled for April 26.

Please help us get the word out about this opportunity by forwarding this message to contacts in your network. Please refer to the NC IDEA Web site (<http://www.ncidea.org/grantsandloans.html>.) for additional information. If you have any additional questions, reply to grants@ncidea.org.

NC Biotechnology Center Creates New Loan Program

The North Carolina Biotechnology Center has launched a program to match Biotechnology Center loans of up to \$250,000 with "angel network" or venture capital investments to help bootstrap biotechnology companies in the state.

The Strategic Growth Award loan program offers a new option to start-up companies facing the cash crunch that sometimes hits between early-stage seed funding and later investment from venture capitalists, business partners and shareholders.

The North Carolina Biotechnology Center has provided loans to new biotechnology ventures for more than 20 years, primarily targeting start-up company research. But the SGA loan isn't restricted to research funding. Rather, these funds can also be used for hiring key non-executive employees, helping to secure patent rights, pursuing business development and licensing opportunities and other purposes that don't include brick-and-mortar outlays. "We see a growing need for this kind of 'bridge' money," said Ken Tindall, the Biotechnology Center's senior vice president, Science and Business Development. "This new SGA loan is the latest example of the North Carolina Biotechnology Center responding to help meet the critical financing needs of early-stage biotechnology companies."

SGA loans must be matched by an equal investment or loan from an angel network or venture capital fund. The SGA money can't be used for physical facilities or to compensate corporate executive officers, though these restrictions don't extend to the matching investments. The SGA program is open only to North Carolina-based biotechnology companies involved in life sciences, natural products or agriculture and in veterinary, environmental or industrial endeavors.

Qualifying companies must show that the loan and matching investment would lift the company to new commercial milestones likely to woo follow-on investors, said John Richert, vice president of the Biotechnology Center's Business and Technology Development Program.

Registration Opens for Tri-state SBIR Conference: March 21-23

Research, Development, and Funding Opportunities for Entrepreneurs and Innovators

**The Wyndham Hotel – Roanoke, VA
March 21 – 23, 2006**

EXPLORE how to grow your business through the interests of the federal government

NETWORK with Federal agency representatives, industryexperts and SBIR/STTR veterans

LEARN how to fund your R&D projects through non-traditional resources

MEET with Federal Agency representatives from NIH, DoD, USDA, DHS, NSF & DOE

Accommodations: Room Rate \$68 + tax ("Tri-State Forum room block) - Cut-off date Feb. 23, 2006, toll-free 877-999-3223

Registration: *NC Attendees call 919-962-8297*

Fees: *\$75 (before 3/16) and \$125 after*

North Carolina Sponsors
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SBIR Success in North Carolina *Cognosci*

Cognosci has discovered a way to harness the therapeutic potential of apolipoprotein-E or apoE, a protein that is naturally produced in healthy people. Originally, apoE protein was thought to regulate cholesterol and fat metabolism, but it is now very clear that apoE also acts to reduce inflammation. The body uses inflammation as its first response to injury or disease, however, intense short episodes of (acute) inflammation or prolonged (chronic) inflammation both result in significant damage to normal healthy tissue when improperly controlled. Cognosci actively strives to develop and commercialize its anti-inflammatory drugs that mimic the apoE protein as an effective way to treat acute and chronic inflammatory diseases.

To find the best anti-inflammatories and improve the likelihood of finding compounds that will perform in humans, Cognosci employs a progressive drug-screening cascade. In our approach, genetic data must be available to show that the apolipoprotein-E gene is directly involved, or is a significant risk factor for the presence and evolution of the disease. Cognosci then uses cellular and organismal models of these genetically validated human disease targets to rapidly test its "COG" compounds that mimic the apoE protein. COG compounds that reduce the inflammation and severity of illness in these models of human disease become pharmacogenomically validated development candidates for human clinical trials.

In national competitions where panels of experts judge and rank proposals based on scientific rigor, innovation, significance, and potential benefit to the public health, Cognosci's scientists have received over a dozen SBIR awards to date and several new Phase 1 and Phase 2 SBIR awards. Each of these SBIR grants has permitted the discovery of novel COG compounds and their validation in models of human disease. The most recent awards include support of enhancement strategies designed to improve COG compound performance in a model of traumatic brain injury. Support was also granted for exploratory research to determine the efficacy of COG compounds in models of multiple sclerosis and of human arthritis in collaboration with physicians at Duke, University of Rochester, Georgetown and UNC-Chapel Hill. Funding of these pharmaceutical research and development efforts is absolutely essential for entry into human clinical trials, for future private investments and for partnerships with Cognosci.

Cognosci currently employs 7 scientists and a medley of individual experts to power its drug finding and development efforts. Founded in 2000 by Dr. Michael P. Vitek, who is also a faculty member of Duke University Medical Center, Cognosci has created a unique funding framework with the help and advice of local and national agents. As one of 32 incubators in North Carolina, the First Flight Venture Center has housed and advised research and business

operations for Cognosci. The NC Small Business Technology and Development Center continues to provide important information that allows scientists to develop and maintain a successful entrepreneurial business. Although Cognosci continues to advance toward private funding/partnerships, current support of the company derives from the Department of State, the Department of Energy and the National Institutes of Health's Small Business Innovation Research grants programs.

TECHLAW: Warning to SBIR/STTR recipients – Failure to mark your deliverables may result in unrestricted disclosure to your competitors

By: Caroline Horton Rockafellow, Daniels Daniels & Verdonik, P.A.

Those of us involved in the entrepreneurial community are all keenly aware of the impact that SBIR (Small Business Innovation Research) and STTR (Small Business Technology Transfer) funding has for small companies working to develop, grow and move to the next level. It is a funding mechanism that has proven to be a lifeline for many entrepreneurial companies. Without this source of funding, many technologies companies would not have gotten off the ground and key technology that we rely on today would not ever have been developed. Now, however, there is a new and very dangerous risk related to use of these development funds. If the technology is delivered to the granting agency without the proper marking, that agency may be able to make unrestricted use and disclosure of the technology.

Government Rights Under the SBIR/STTR Programs

Under the SBIR and STTR programs, certain federal agencies are required to reserve a portion of the federal research and development budget for grants and contracts aimed at small business concerns. The intent is that these funds will be used in the small business community to develop technology and scientific advances that will be of future commercial benefit. Under the Bayh-Dole Act, the legislation that governs transfer of ownership and control of government funded inventions, principal worldwide patent rights to an invention supported in whole or in part with Federal funds may be retained by the small business subject to an obligation to report all such inventions to the granting agency.

The granting agency retains a nonexclusive license to practice the invention on behalf of the government, but the Bayh-Dole Act does not allow the government to compete with the small business for licensing of the invention. All SBIR and STTR recipients are aware that the granting government agencies have certain "march-in" rights with respect to the technology developed under an SBIR or STTR. Historically, this has not been a problem, and there are very few cases where the government has exercised its march-in rights under such agreements. However, there is now a much larger issue to consider with respect to intellectual property rights and SBIR or STTR grants. That concern is the right the government agencies may have to deliver confidential and proprietary information and materials to third party competitors for the purpose of encouraging such third party to compete with the grantee company. The potential risk for the small business is far more onerous than any concern related to march in rights ever could have been.

The Troublesome Scenario

Imagine the following situation: An entrepreneurial company is fortunate enough to win a Small Businesses Innovation Research (SBIR) grant. As a part of the contract, the company engages a subcontractor to assist in the development work. The subcontractor and company have a falling out, the subcontractor makes demands on company outside of the original contract and the relationship becomes adversarial. The company successfully completes its Phase I and Phase II SBIR work and delivers a prototype to the granting agency, as required under the SBIR grant. The company then applies for Phase III funding from the government agency. The government agency does not engage the original grantee company for Phase III, but rather seeks out the problematic subcontractor and engages the subcontractor to perform the final commercial development of the technology developed by the original grantee under the SBIR Phase I and Phase II grants. Worse yet, the government agency delivers all of that company's confidential and technical information to the subcontractor for use in subcontractor's development of the commercial product. This should be a completely fictitious scenario, but, unfortunately, it is a real fact pattern and an actual holding from a recent case decided by the United States Court of Federal Claims.

Night Vision Corp. vs. the United States of America

In November of last year, the United States Court of Federal Claims issued its opinion in the case of *Night Vision Corp. vs. the United States of America*. The plaintiff, Night Vision Corp. ("NVC") claimed that the Air Force violated the SBIR prohibition against disclosing third party proprietary data when the Air Force delivered NVC's prototypes developed under the SBIR to NVC's competitor and former subcontractor, Insight Technologies, Inc. ("Insight"). It is generally understood that technical data is protected from government disclosure, provided that the appropriate legends are affixed to the technical data. Whether the prototypes delivered by NVC to the Air Force constituted "technical data" was disputed by the parties, but, nevertheless, the Court found that even if the prototypes were found to be technical data and subject to the protections afforded technical data under SBIR contracts, NVC had waived its rights by not affixing the restricted rights legend directly to the prototype. Although the Court agreed that the Air Force would be restricted under the SBIR contract from disclosing or delivering the prototypes to NVC competitors, it found that the failure of NVC to clearly mark the prototype with the prescribed legend effectively waived NVC's rights in the prototypes and provided the government with complete and unrestricted use of the prototypes.

This finding has and should send chills through the SBIR community. It should also raise significant concerns for any entity that works under government grants or contracts. Not only can the government assert rights in inventions if the company fails to commercialize the technology, but now if technology is delivered without proper marking the government can also make an unrestricted disclosure of the technology to third parties. Worse yet, this confidential technology can be delivered to the developing party's competitors and used against it in a competitive bidding process.

What Does This Mean?

The fact pattern of this particular case is extremely disturbing. On the face of the case, it appears that the Air Force was able to secure rights in technology owned by one of its SBIR recipients for the purpose of transferring such technology to a third party competitor of that SBIR recipient. Whether this action was taken because the third party was technically more adept

and the Air Force believed better able to move the technology to a commercial product, or whether it was because the third party had better political connections within the granting agency, is unclear. What is clear is that rights were lost because prototypes were not properly marked.

The plaintiff in this case will likely appeal the ruling, and it is possible the case could be overturned. In the meantime, this case should serve as a warning to all entities working under government contracts. Not only must such entities be extremely careful and establish all the proper administrative procedures to ensure that reporting and record keeping requirements are met, but such entities must also closely screen all disclosures and deliveries made under the government contract or grant to ensure that all proper markings are in place.

Conclusion

Whether or not this ruling is upheld, the fact pattern of this case should cause significant concern for all parties involved with any government contracts, and specifically SBIR and STTR grants. The SBIR/STTR program is an invaluable program that has significantly promoted the advancement of science and technology in this country. It is disheartening to think that such programs could be put at risk if the most promising of recipients no longer believe that their technological innovations are safe from the reaches of their competitors. This case and the resulting fall out will be closely monitored. In the meantime, all SBIR/STTR recipients must closely review their administrative procedures when it comes to making deliveries and disclosures to the granting agency.

Daniels Daniels & Verdonik, P.A. has been serving the legal needs of entrepreneurial and high technology clients for more than 20 years. Caroline Horton Rockafellow concentrates her practice in the representation of entrepreneurial and technology-based business, focusing on corporate, technology and licensing matters. Questions or Comments can be sent to crockafellow@d2vlaw.com.

Websites Worth Review

Grants.gov: Funding opportunities government-wide at: <http://www.grants.gov>

NIH Electronic Submission: Learn all about the process at <http://era.nih.gov/ElectronicReceipt/>
