



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

July 7, 2003

Mr. Gary M. Jackson
Assistant Administrator for Size Standards
Office of Size Standards
U.S. Small Business Administration
409 Third Street SW.
Washington, D.C. 20416

Dear Administrator Jackson:

The Biotechnology Industry Organization (BIO), is pleased to respond to the request for comments on the U.S. Small Business Administration's (SBA) Proposed Rule to modify the small business eligibility requirements for receiving Small Business Innovation Research Program (SBIR) funding (68 FR 33412) published on June 4, 2003.

BIO is a trade association representing over 1000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. Our membership represents a complete cross-section of the industry, from small, research-based start-ups to mid-sized and large well-established biotechnology companies. The vast majority of BIO members are emerging companies focusing on the research and development of new products, goods or services flowing from biotechnology.

Before most biotechnology products can become commercially available, years of work and hundreds of millions of dollars of investment capital are required to complete adequate testing and to gain product approvals. While there are many different funding strategies, the typical form of investment in promising, early-stage companies is venture capital. Such capital comes from venture funds, whose partnership interests are usually owned by individual investors and pension funds. After the initial seed funding is invested in support of basic R&D, a typical biotechnology company seeks venture capital investment to allow it to launch its commercial operations. Simply put, very few biotechnology companies are capable of commercializing

1225 EYE STREET, N.W., SUITE 400
WASHINGTON, D.C. 20005-5958

WDC - 65682/0015 - 1763952 v2

202-962-9200
FAX 202-962-9201
<http://www.bio.org>

their technologies without significant VC backing. VC investments in the biotechnology and medical device industry totaled \$4.7 billion in 2002¹.

Background

The SBIR program regulations require that, to be eligible for SBIR grants, companies must be “small” (<500 employees) and “[a]t least 51 percent owned and controlled by one or more *individuals*.” 13 C.F.R. § 121.702 (emphasis added). Based primarily on a relatively recent SBA Office of Hearings and Appeals (OHA) decision, the SBA has interpreted the word “individuals” to mean only “natural persons” . . . See *CBR Laboratories, Inc.*, SBA No. 4423. As indicated by the Preamble to the Proposed Rule, however, it quickly became clear to the SBA that *CBR Laboratories* created an unreasonably narrow SBIR eligibility standard because agencies participating in the SBIR program often received proposals from a “concern that is owned by another concern [and] [t]he concern’s size, together with its parent company, will often be below the 500 employee size standard for an award, while its parent is at least 51 percent owned and controlled by one or more U.S. citizens or permanent resident aliens”. 68 Fed. Reg. 33,412 (June 4, 2003). Under the strict interpretation articulated in *CBR Laboratories*, such a company would be ineligible for SBIR funding. The Proposed Rule is intended to restrict the scope of *CBR Laboratories* by finding that a company falling within the above-referenced scenario would be eligible for SBIR funding.

Although BIO fully supports the Proposed Rule’s effort to restrict the application of *CBR Laboratories*, recent events demonstrate that the rule must be further revised because OHA continues to impose unduly restrictive SBIR eligibility standards. Specifically, the National Institutes of Health (NIH)—one of the agencies participating in the SBIR program — has recently applied *CBR Laboratories* to revoke a SBIR grant awarded to an otherwise eligible small business that had significant venture capital and pension investors. OHA upheld the appeal of the agency’s decision, and in doing so ruled that the word “individuals” in the SBIR size standard excluded not only corporations but also all other forms of artificial entities, including venture capital and pension funds. See *Cognetix, Inc.*, SBA No. 4560. By revoking an award to an otherwise eligible small VC-backed biotechnology company, NIH created another form of the problem that the Proposed Rule was designed to cure.

The impact of the *Cognetix* decision is immediate and severely negative for the emerging biotechnology industry—especially in the current economic climate in which SBIR awards are even more important because of the scarcity of capital. Removing this important funding source for early stage biotechnology companies would penalize the most promising small companies, i.e. those able to win VC backing as well as SBIR funding. In companies that are backed by venture capital funds, the venture capital

¹ Money Tree Survey –Price Waterhouse Coopers, www.pwcmoneytree.com

investment funds generally own more than 51 percent of the company and the “individual” shareholders are the founders, employees, friends of the company, and angel and family investors. This typical combination of venture funding and only modest investment directly by individuals, boosts “non-individual” ownership above the 51 percent level very early in a company’s existence and, in virtually every instance, would render the small business ineligible for SBIR funding. Very few, if any, biotechnology companies are able to fund the clinical and preclinical work needed to validate a technology without venture investment – the cost of development is simply too high to be sustained by individuals. The legislative history of the SBIR program makes it abundantly clear that Congress intended for the SBIR program to assist small businesses to commercialize. Indeed, when Congress enacted the SBIR program through the Small Business Innovation Development Act (P.L. 97-219), it recognized the crucial relationship between venture capital and SBIR program in commercializing promising technologies.

Changes Proposed in the Pending Rulemaking

The Proposed Rule would continue to apply the “51 percent” test but would clarify that a company may be eligible for SBIR funding if it is 100 percent owned by an entity which, in turn, is 51 percent or more owned by “individuals” (who are U.S. residents). Unfortunately, this modification does not address the problem biotechnology companies with venture capital backing are experiencing. As noted above, VC-backed companies are usually more than 51 percent owned by VCs but they are never 100 percent owned by VCs. Moreover, VCs, as entities, are not 51 percent or more owned by US “individuals”.

Recommended Changes to the Proposed Rule

Congress’ intent, when implementing the SBIR program, was to *stimulate small U.S.-owned firms to produce innovative technologies*. When Congress first enacted the SBIR program, it very clearly recognized the symbiotic relationship between venture capital and the SBIR program it was creating and expressly intended to encourage and strengthen that important connection. See S. Rep. No. 97-194, 97th Cong., 1st Sess. 1981, *reprinted in*, 1982 U.S.C.A.A.N. 512. For example, there is an entire section of the relevant Committee report detailing the importance of encouraging private investment. Indeed, the Committee concluded that concluded that

providing small firms with R&D seed money . . . will encourage additional private investment in these firms. The agency-wide SBIR program outlined in the legislation should facilitate the ability of participating firms to attract venture capital as well as other financial commitments from the private sector.

See Committee Report at 7. Thus, the SBIR program was viewed by Congress as providing the necessary “proof of concept” to encourage venture capital investment in promising small businesses.

Moreover, Congress even went so far as to provide “special consideration in the funding review of Phase II proposals to applicants who are successful in attracting private capital commitments to pursue commercial applications of the Federal research. This special consideration is given by awarding extra points of merit to those proposals that have attracted private sector commitments for follow-on funding.” Report at 7-8. Thus, Congress created a Phase II SBIR preference for companies that attracted venture capital investment. Application of the “51 percent” rule is clearly at odds with Congressional purposes.

Small biotech companies that are successful in attracting venture capital investment are, therefore, a paradigm of SBIR success. Attracting outside capital investment is not only the clear intent of the SBIR program, it is also the type of success that Congress recognized as meriting *more* SBIR support in the form of a Phase II award preference. The current interpretation of the word “individuals” simply cannot be squared with Congressional intent to encourage venture capital investment in small businesses. Without revising the Proposed Rule to correct the *Cognetix* decision, SBA will be foreclosing the very companies that the SBIR program was designed to assist from receiving SBIR awards.

Recommended Changes to the Proposed Rule

BIO recommends that SBA expand the Proposed Rule to allow small businesses with venture capital investors to participate in the SBIR program. This could be accomplished by providing that investments by venture capital be ignored when assessing whether there is 51% ownership. This is analogous to the exception in the affiliation rules under which venture capital investments are ignored in determining the eligibility of companies for small business status. 13 C.F.R. § 121.103(5)(i).

BIO commends the SBA for attempting to address the concerns of small business owners and urges the SBA to make appropriate changes to the current and proposed regulations in order to exclude ownership by venture capital firms as a factor in determining SBIR eligibility. We request that application of these changes be made retroactive to allow companies previously awarded SBIR grants, whose grants were revoked due to the current interpretation of the regulations, the opportunity to continue to receive funding from this important source.

Please contact me at 202-962-9215 or Lila Feisee at 202-962-9502 if you have any questions about these comments.

Sincerely,

BioTechnology Industry Organization

Stephan E. Lawton
Stephan E. Lawton *AD*

Vice President and General Counsel

Morrie Ruffin

Morrie Ruffin *AD*
Vice President

Business Development