



April 5, 2021

Dr. Silverthorn

<http://www.nist.gov/tpo/bayh-dole>

Robert Schmidt
Kevin Burns
Co-Chairmen

Jere Glover
Executive Director

Re: Request for Comments on Rights to Federally Funded Inventions and Licensing of Government Owned Inventions. Docket No. 201207-0327.

Larry Nannis
Treasurer

Dear Dr. Silverthorn,

Matt Oristano
Mid-Atlantic
Regional Chair

Ash Thakker
Southeast
Regional Chair

Mary Delahunty
Southwest
Regional Chair

Russ Farmer
Mountain
Regional Chair

Michael Browne
Pacific
Regional Chair

Roy Keller
State Liaison

Paul Donovan
Michael Squillante
NIH Committee
Co-Chairs

Ash Thakker
Phase III Committee
Chair

Russ Farmer
DCAA Committee
Chair

Jonathan Kaplan
Patent Committee
Chair

The Small Business Technology Council (SBTC) is pleased to submit comments on the above-captioned Request for Comments on NIST's proposed changes to 37 CFR 401 *et seq.* SBTC is the nation's largest association of small, technology-based companies in diverse fields. We are a council of the National Small Business Association (www.NSBA.biz) which is the nation's first small-business advocacy organization. NSBA is a staunchly nonpartisan organization with 65,000 members in every state and every industry in the U.S. SBTC advocates on behalf of the 6000 firms who participate in the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

SBIR/STTR firms have created over 20 percent of America's major innovations, despite receiving less than 5% percent of Federal R&D funding.¹ SBIR/STTR firms generate as many patents as all universities combined, and they produce 16 times more patents per employee than large patenting firms. It is also highly likely that SBIR/STTR companies as a group are the major licensee of university created technology.

Small business innovation has a substantial positive impact on employment and American prosperity. The Federal Reserve found that patents are the number one indicator of regional wealth.² Being a high patenting community means the difference of \$8,600 in household income.³

Technology-focused small businesses contribute new technology, competitive strength and high-quality job vitality to the American economy. Such businesses depend on strong and predictable patent rights to survive. Patent regulations that increase uncertainty and add unnecessary costs stifle innovation and add anti-competitive barriers to entry against such high-tech small businesses and their new technologies, while protecting the market share and power of large companies and incumbent technologies. These small innovative companies take substantial risk to power the American economy. Without the foundation of stable, accessible, and defensible patent rights, small business simply cannot obtain the return-on-investment necessary to justify those risks and secure capital.

In NIST's proposed changes shown at <https://www.regulations.gov/document/NIST-2021-0001-0001>, NIST proposes the following change to 37 CFR 401.6.



(7) Clarify § 401.6 to include a provision that march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the **pricing** (emphasis added) of commercial goods and services arising from the practical application of the invention.

SBTC OBJECTS to this proposed change. Nowhere in the Bayh-Dole Act (the relevant portion on march-in rights, shown below) does the Act require, imply, or even suggest that pricing be made part of the decision-making process.

"§203. March-in rights

"With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—

"(a) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

"(b) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

"(c) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or "(d) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

March-in rights were meant to prohibit the licensee from keeping an invention from being practiced either by purposefully sitting on the invention to protect prior technology of the licensee, or for a company who cannot or will not produce a commercial product. Price is not a factor in March-in rights.

SBTC supports and advocates the comments separately provided by Joseph Allen, the principal Senate staffer responsible for the passage and implementation of the Bayh-Dole Act. Mr. Allen not only discusses the original intent of the Act but also highlights that the Act contains no language referencing favorable or unfavorable to the Government price as consideration in exercising march-in rights.

Adding the NIST proposed clause will add uncertainty for Government personnel, inventors, companies, and investors. This will have the opposite affect than what is intended. By increasing uncertainty, the Government will reduce innovation, decrease patenting, lower wealth creation, and reduce the number of new jobs created; all bad for the American economy and for small business.

If the Government believes that the pricing is more than what it is willing to pay, it should use prior technology. Taking a technology from the licensee solely to save money falls within the 4th Amendment (Seizure) and the 5th Amendment Takings clause and is



unconstitutional. Thus, the Government must not renege on its license without due process and paying fair compensation. But it is better to not renege at all, and to strengthen the patent system, small inventing businesses, and the American economy.

If NIST insists on adding subparagraph 7, we suggest it be revised as suggested by Joe Allen as follows.

“March-in rights shall not be exercised based on the business decisions regarding the pricing of commercial goods and services arising from practical application of the invention.”

SBTC cannot support another dilution, weakening, or confusion of patent rights, by allowing the Government to not only negate an SBIR/STTR company’s rights (like they do with the PTAB), but worse, remove those rights and give those patent rights to others. This would mean the SBIR/STTR company can no longer even non-exclusively practice the invention. This is the worst of all worlds because if an SBIR/STTR company is asking for an excessive price for its product, as determined solely by in the Government, the Government can take away not only the invention, but all the investment the company has made in further developing the invention. This will have a tremendous chilling effect on new technology development in America. It will further degrade and accelerate America’s fall from #1 to #11 in innovation.⁴ Further, the United States fell from its long-standing position as number one to twelve in Patent Strength,⁵ behind countries such as France, Sweden, Japan, Great Britain, and Singapore⁶ and NIST’s proposed change will make this worse.

This proposed change by NIST will make America poorer and less competitive. Furthermore, over time, it will degrade the health of Americans and the world by reducing the number of new drugs and medical devices in the future as the new proposed NIST regulation will discourage investment in new technologies. We are concerned that NIST’s proposed regulation change will cause more severe pandemics over the next century as drug developing scientists and engineers move to other careers, reducing or eliminating our capability to fight the germ of the future.

Although this may be deemed as farfetched, some might even conclude NIST’s proposed change could possibly end humanity by decimating the drug industry in the United States, the drug development capital of the world;⁷ as the US accounts “for 42% of prescription drug spending and 40% of the total GDP among innovator countries and was responsible for the development of 43.7% of the NMEs” (new molecular entities). In any case, NIST’s proposed change will have significant “unintended” consequences that can easily be foreseen by weakening America’s innovation ecosystem.



SBTC is pleased to continue its support of NIST and the strengthening of patent rights, particularly for small businesses and individual inventors. Please feel free to contact me with any questions at rschmidt@CleveMed.com or on my cell phone at 216-374-7237.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert N. Schmidt", is written over a light gray, semi-transparent signature strip.

Robert N. Schmidt
Co-Chair
Small Business Technology Council
Patent Attorney (USPTO #30,889)
Professional Engineer (Ohio, #40,821)

References:

¹ Testimony before the Senate Small Business and Entrepreneurship Committee, May 15, 2019, Small Business Technology Council (SBTC), Jere Glover, Executive Director Robert N. Schmidt, Kevin Burns, & Alec Orban, <https://sbtc.org/wp-content/uploads/2019/05/Jere-Glover-Testimony-5-24-Revised.pdf>

² Federal Reserve Bank of Cleveland, "Altered States: A Perspective on 75 Years of State Income Growth," *Annual Report 2005*. For more detail, see Paul Bauer, Mark Schweitzer, Scott Shane, *State Growth Empirics: The Long-Term Determinants of State Income Growth*, Working Paper 06-06, Federal Reserve Bank of Cleveland, May 2006, <https://www.clevelandfed.org/newsroom-and-events/publications/annual-reports/ar-2005-perspective-on-75-years-of-state-income-growth/ar-200502-altered-states-essay.aspx> by Bauer *et. al.*

³ Patenting Prosperity: Invention and Economic Performance in the United States and its Metropolitan Areas Jonathan Rothwell, José Lobo, Deborah Strumsky, and Mark Muro. At \$4,300 per worker, that is \$8,600/year for a two worker household. <https://www.brookings.edu/wp-content/uploads/2016/06/patenting-prosperity-rothwell.pdf> page 15.

⁴ Germany Breaks Korea's Six-Year Streak as Most Innovative Nation, Michelle Jamrisco and Wei Lu, January 18, 2020, <https://www.bloomberg.com/news/articles/2020-01-18/germany-breaks-korea-s-six-year-streak-as-most-innovative-nation>.

⁵ Germany Breaks Korea's Six-Year Streak as Most Innovative Nation, Michelle Jamrisco and Wei Lu, January 18, 2020, <https://www.bloomberg.com/news/articles/2020-01-18/germany-breaks-korea-s-six-year-streak-as-most-innovative-nation>.

⁶ US Chamber International IP Index, Sixth Edition, February 2018, Figure XI: Scores, Category 1: Patents, Related Rights, and Limitations. https://www.uschamber.com/sites/default/files/023331_gipc_ip_index_2018_opt.pdf.

⁷ US Pharmaceutical Innovation in an International Context, *Am J Public Health*, 2010 June; 100(6): 1075–1080, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2866602/>