

October 21, 2024

The Honorable Monica M. Bertagnolli, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Director Bertagnolli,

As Ranking Member of the U.S. Senate Committee on Small Business and Entrepreneurship, I am greatly concerned about the National Institutes of Health (NIH) issuing federal awards through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs that have funded patents for China-based inventors in critical technology areas. Records from the public database of the United States Patent and Trademark Office (USPTO) show that over the past decade, at least 26 patents awarded to China-based inventors were funded, all or in part, by NIH SBIR-STTR awards. These awards, made to ten companies prior to 2022, resulted in patents affiliated with China-based researchers.¹ These ten identified companies collectively received just under \$50 million in SBIR-STTR awards.² As a result, American taxpayer funded research and development (R&D) is now exposed to potential exploitation by the Chinese Communist Party (CCP).

Most troubling, however, is how much of this U.S.-funded intellectual property (IP) relates to critical technology areas, such as biotechnology. A 2020 NIH SBIR award funding a clinical trial of a immunomodulator therapeutic to treat COVID-19 resulted in a patent being held by three China-based inventors.³ It is truly egregious for the federal government to fund a patent held by Chinese inventors for a pharmaceutical combatting a deadly virus widely known to have arisen from a leak from a Chinese lab which works on secret projects with the Chinese military.⁴ Additionally, a 2016 NIH Phase II SBIR grant funded a patent with a China-based inventor for a

¹ USPTO, PATENT PUBLIC SEARCH, available at <https://ppubs.uspto.gov/pubwebapp/> (last accessed on Sept. 16, 2024). See Attachment A.

² See W-Z Biotech LLC: \$3,998,876; Microsensor Labs: \$4,725,025; Preclinomics: \$2,640,010; DiscoveryBioMed Inc.: \$11,512,428; Oncoimmune Inc.: \$7,026,474; Trim-edicine: \$5,922,393; Stemmed LTD.: \$1,992,190; Paratus Diagnostics, LLC: \$2,817,504; Alliance Discovery: \$1,835,930; Nanomaterials and Nanofabrication Laboratories: \$7,156,088, SMALL BUS. ADMIN., SBIR PORTFOLIO DATABASE, available at <https://www.sbir.gov/portfolio> (last accessed on Sept. 16, 2024).

³ See SMALL BUS. ADMIN., SBIR PORTFOLIO DATABASE, SAC-COVID: An FDA-approved Phase III Clinical Trial Evaluating the Safety and Therapeutic Efficacy of cd24Fc in Severe COVID-19 Patients, Awardee: Oncoimmune Inc., available at <https://www.sbir.gov/awards/176656>; see also NIH, AN FDA-APPROVED PHASE III CLINICAL TRIAL EVALUATING THE SAFETY AND THERAPEUTIC EFFICACY OF CD24FC IN SEVERE COVID-19 PATIENTS, Project Details, Project Number: 3R44CA246991-02S1, available at <https://reporter.nih.gov/search/bhM2Z0O26EaN2cZ9ZrGYwA/project-details/10145067>.

⁴ U.S. DEPT OF STATE, FACT SHEET ACTIVITY AT THE WUHAN INSTITUTE OF VIROLOGY, (JAN 15, 2021), available at <https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology/>

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novel technological intervention for certain congenital heart anomalies, potentially a key medical advancement.⁵

American tax dollars intended to fuel innovation domestically being sent to China proves the necessity of the foreign ties due diligence requirements enacted in the *SBIR and STTR Extension Act of 2022*.⁶ Across our federal R&D landscape, we must defend America's research security now more than ever, as our adversaries work overtime to exploit our world-class technological developments. It is unacceptable that American taxpayer dollars are funding IP for the potential benefit of America's number one pacing threat. Government research dollars must be directed towards fostering innovation in the United States, especially in critical technology areas. It is a grave risk to our national competitiveness and security for China to benefit from America's investment in emerging technologies.

The *SBIR and STTR Extension Act of 2022*, which I championed, requires all agencies with an SBIR-STTR program to implement a "due diligence program to assess security risks" that analyzes "the cybersecurity practices, patent analysis, employee analysis, and foreign ownership of a small business" applying for an award.⁷ This was a positive step. But these new revelations of Chinese inventors receiving patents for U.S. taxpayer-funded research and technology underscore the need for increased scrutiny over these processes and for program managers to guard our critical research ecosystem from adversaries.

Make no mistake, American taxpayer dollars funding patents for China-based inventors extends beyond the SBIR-STTR program and NIH. USPTO data shows the federal government has funded more than 1,000 patents for China-based inventors since 2010.⁸ From NIH R-01 grants to Defense Advanced Research Projects Agency research funding, millions of U.S. taxpayer dollars are funneled to IP development for China-based inventors.⁹ Many of these patents are in critical technology areas such as biotechnology and semiconductors.

As Ranking Member of the U.S. Senate Armed Services Subcommittee on Emerging Threats and Capabilities, I have championed a provision in the *Fiscal Year (FY) 2025 National Defense Authorization Act (NDAA)* to place much-needed limitations on the Department of Defense (DoD) research grants and contracts going to universities conducting fundamental research with Chinese universities on DoD's list of "Foreign Institutions Engaging in Problematic Activities to Counter Unauthorized Technology Transfer." Every dollar flowing to a Chinese researcher is a resource directed away from American innovators. You must redouble your efforts to stop this practice once and for all.

⁵ See SMALL BUS. ADMIN., SBIR PORTFOLIO DATABASE, Development of Percutaneous DLC for Total Cavo pulmonary Assistance, Awardee: W-Z Biotech LLC, available at <https://www.sbir.gov/awards/160096>.

⁶ SBIR and STTR Extension Act of 2022, P.L. 117-183.

⁷ 15 U.S.C. § 638(vv).

⁸ Michael Martina, Exclusive: US Government funding yielded hundreds of patents for China-based researchers, REUTERS, (Aug. 29, 2024), available at <https://www.reuters.com/world/us-government-funding-yielded-hundreds-patents-china-based-researchers-2024-08-29/>.


⁹ USPTO, PATENT PUBLIC SEARCH, available at <https://ppubs.uspto.gov/pubwebapp/> (last accessed on Sept. 16, 2024). See USPTO Document ID US 20220105152 A1 in Attachment A and Attachment B.

The SBIR and STTR program authorizations lapse on September 30, 2025. As this deadline approaches, I am continuing to evaluate what changes are needed to strengthen our efforts to protect small businesses' intellectual property. To assist me in my oversight, and to improve the operation of these programs, please provide written answers to the following questions no later than November 4, 2024:

1. How does NIH screen for risk of intellectual property exposure to China-based investors as part of its foreign ties due diligence process within the SBIR-STTR program?¹⁰
 - a. How does the current due diligence process examine the established patent record of SBIR-STTR applicants for risky foreign ties?
2. Following the implementation of the required foreign ties due diligence process in the SBIR-STTR program, how many awards has NIH granted to companies with China-based researchers?
3. How many SBIR-STTR applicants to NIH have been identified as at-risk for foreign adversarial influence through "patent analysis"—as required by 15 U.S.C. § 638(vv)—since January 1, 2023?
 - a. Of those identified as at-risk through "patent analysis," please provide a breakdown of application outcomes including the number of applicants granted and the number of applicants denied an SBIR or STTR award.

Thank you for your prompt attention to this important matter. If you have any questions about this request, please do not hesitate to contact me or Meredith West on my staff at (202) 224-5175.

Sincerely,



Joni K. Ernst
Ranking Member

cc: Dr. Stefanie Tompkins, Director
Defense Advanced Research Projects Agency

Enclosures -
Attachment A – NIH SBIR-STTR Funded Patents
Attachment B - DARPA Funded Patents

¹⁰ SBIR and STTR Extension Act of 2022, P.L. 117-183.

Appendix I¹¹

NIH SBIR-STTR Funded Patents

SBIR-STTR Company Name	Agency/SBIR-STTR Award	SBIR-STTR Award Date	First Patent Date Published	USPTO Patent ID(s)	China-Based Inventor(s)
Oncoimmune, Inc.(Acquired by Merck)	NIH NCI: SBIR Phase II R44CA246991	September 17, 2019	April 6, 2023	US 20230103352 A1	Xianfeng Fang, Dongling Li, and Libing Mu
Trim-Edicine, Inc.	NIH: SBIR Phase II R44DK112403 and SBIR Phase II R44GM123887	September 15, 2016; April 1, 2019	April 7, 2022	US 20220105152 A1	Chunyu Zeng and Yu Han
W-Z Biotech, LLC	NIH: SBIR Phase II R44HL 129490	August 15, 2016	August 12, 2021	US 20210244911 A1B32B3:B31	Guangfeng Zhao
Paratus Diagnostics, LLC	NIH: STTR Phase I R41AI126965	July 4, 2016	August 13, 2020	US 20200255891 A1	Sheng Cai
Alliance Discovery Inc.	NIH: SBIR Phase I R43CA183362	September 17, 2014	February 27, 2020	US 20200062768 A1; US 11267817 B2; US 20220144845 A1	Xin Feng
PreClinOmics (Acquired by Crown Bioscience)	NIH: SBIR Phase II R44DK082065	June 18, 2012	December 27, 2018	US 20180369423 A1; US 11020494 B2	Gao Sun and Guodong Zhang
Microsensor Labs, LLC	NIH: SBIR Phase I R44AG060848 and SBIR Phase I R43NR017372	July 15, 2019; February 15, 2018	October 11, 2018	US 20190043337 A1; US 9815825 B2; US 10679488 B2; US 20180293873	Yang Liu

¹¹ USPTO, PATENT PUBLIC SEARCH, available at <https://ppubs.uspto.gov/pubwebapp/> (last accessed on Sept. 16, 2024); SMALL BUS. ADMIN., SBIR PORTFOLIO DATABASE, available at <https://www.sbir.gov/portfolio> (last accessed on Sept. 16, 2024); See Attachment A.

				A1; US 10403121 B2; US 20200005623 A1; US 10748410 B2	
Nanomaterials and Nanofabrication Labs	NIH: SBIR Phase II R44GM069065	August 21, 2008	February 16, 2016	US 9260652 B2	Renguo Xia
DiscoveryBioMed, Inc. (Acquired by Euofins Discovery)	NIH NIDDK: SBIR Phase II R44DK084658	September 12, 2012	October 22, 2015	US 20160024065 A1; US 9815825 B2; US 20150307503 A1; US 20150299206 A1; US 9546176 B2	Hongwu Gao
StemMed, Ltd.	NIH: STTR Phase I R41CA153658	September 26, 2012	January 29, 2015	US 20200331880 A1; US 11161831 B2; US 20150031714 A1; US 20220227750 A1	Marvin X. Xu