verified the applicant's claim that NDA 215383 was approved on August 13, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 342 days of patent term extension.

**III. Petitions**

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 5, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–27044 Filed 12–8–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Theodoric Mattes at 240–627–3827, or *theodoric.mattes@nih.gov*. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

**SUPPLEMENTARY INFORMATION:** Technology description follows:

**Vaccine for Cats To Block Toxoplasma Gondii Oocyst Shedding and Transmission**

*Description of Technology:*

*Toxoplasma gondii* is the zoonotic causative agent of toxoplasmosis, a disease of significant concern for pregnant persons and livestock. A member of the phylum Apicomplexa, *Toxoplasma gondii* can infect almost any cell type found in mammals and birds. There are multiple transmission pathways, including consumption of undercooked meat from infected animals, consumption of unwashed plants, contaminated water supplies, blood transfers, and congenital transfer. Felines are considered the definitive host of *Toxoplasma gondii.* Direct or indirect transmission can occur via contact with the stool of infected felines.

Researchers at the National Institute of Allergy and Infectious Diseases (NIAID), the U.S. Department of Agriculture (USDA), and the University of South Bohemia (České Budějovice, Czechia) have demonstrated that *T. gondii* strains lacking expression of either the intracellular transport protein IFT88 or the CYS–6-type surface antigen SRS15B prevent the formation of oocysts and have potential for broad immunity to *T. gondii.* The inventors propose that mass inoculation of felines, specifically wild or feral felines, with a live vaccine developed from these strains could result in a significant reduction in oocyst production and environment contamination, reducing further infection in a geographical area. It is also proposed that loss of IFT88 or SRS15B homologs in other Apicomplexa parasites, like *Neospora, Sarcocystis,* or *Cryptosporidium* could have a similar impact.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

*Potential Commercial Applications:*

- Live vaccine for felines against *Toxoplasma gondii* infection
- Reduction in environmental *Toxoplasma gondii* oocysts

*Competitive Advantages:*

- 100% blocked *Toxoplasma gondii* oocyst shedding in felines
- Detectable seroconversion protective against future *Toxoplasma gondii* infection
- Scalable production strain with predictable inactivation of IFT88 or SRS15B gene
- Materials available for development or licensing

*Development Stage:*

- Pre-Clinical

*Inventors:* Michael Grigg (NIAID), Aline Sardinha da Silva (NIAID), Viviana Pszenny (NIAID), Jitender Dubey (USDA), and Julius Lukeš (University of South Bohemia, Czechia).

*Intellectual Property:* HHS Reference No. E–118–2023–2. U.S. Provisional Patent Application No. 63/470,773 filed June 4, 2023.

*Licensing Contact:* To license this technology, please contact Theodoric Mattes at 240–627–3827, or *theodoric.mattes@nih.gov.,* and reference E–118–2023–2.

*Collaborative Research Opportunity:* The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. For collaboration opportunities, please contact Theodoric Mattes at 240–627–3827, or *theodoric.mattes@nih.gov*.

Dated: December 5, 2023.

**Surekha Vathyam,**

*Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.*

[FR Doc. 2023–27113 Filed 12–8–23; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Theodoric Mattes at 240–627–3827, or *theodoric.mattes@nih.gov*. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

**SUPPLEMENTARY INFORMATION:** Technology description follows:

**Recombinant IgG Monoclonal Antibody-Based Detection of Taenia Antigen In Humans And Pigs**

*Description of Technology:* The pork tapeworm, *Taenia solium,* is endemic in most of Asia, Latin America, and Sub-Saharan Africa. The risk of infection is increased in regions where pigs are raised in closed proximity to humans, with migration from endemic regions being directly proportional to the prevalence of infection in high-income countries. Human infection by *T. solium* occurs following oral ingestion of eggs passed in human feces from an infected carrier. The larvae can travel anywhere in the human body. Neurocysticercosis (NCC) occurs when the larvae traverse the blood-brain barrier and penetrate the central nervous system. Diagnosis of NCC is typically made through radiological imaging studies (such as computed tomography or magnetic resonance imaging) to visualize the morphology, stage, and location of the cysts.

Investigators at NIAID have developed the recombinant IgG monoclonal antibody known as TsG10, which can target *T. solium* circulating antigens. An expression vector to produce TsG10 is available for expression in mammalian cell lines. The resulting construct allows for a scalable, repeatable, and broadly accessible production of monoclonal antibodies for both human and veterinary use. The TsG10 monoclonal antibodies are adaptable for plate-based diagnostic assays like ELISAs, to support a diagnosis of NCC.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

*Potential Commercial Applications:*

- Plate-based diagnostic immunoassays, both human and veterinary, for the detection of *T. solium* circulating antigen
- Production of TsG10 recombinant monoclonal antibodies

*Competitive Advantages:*

- Detection of active *T. solium* infection
- Scalable and repeatable production of a monoclonal antibody targeting *T. solium*
- Materials available for development or licensing

*Development Stage:*

- Research Material

*Inventors:* Drs. Thomas B. Nutman, Elise O'Connell, Theodore E. Nash, Siddhartha Mahanty, Hector Garcia, Adriana Paredes, all of NIAID

*Intellectual Property:* HHS Reference No. E–043–2022–0

*Licensing Contact:* To license this technology, please contact Theodoric Mattes at 240–627–3827, or *theodoric.mattes@nih.gov.,* and reference E–043–2022–0.

*Collaborative Research Opportunity:* The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. For collaboration opportunities, please contact Theodoric Mattes at 240–627–3827, or *theodoric.mattes@nih.gov*.

Dated: December 5, 2023.

**Surekha Vathyam,**

*Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.*

[FR Doc. 2023–27114 Filed 12–8–23; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Brian Bailey, Ph.D.; 240–669–5128 or 301–201–9217; *bbailey@mail.nih.gov*. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852: tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

**SUPPLEMENTARY INFORMATION:** Technology description follows:

**Enhanced Immune Response With Stabilized Norovirus VLPs: A Next-Generation Vaccine Approach**

*Description of Technology:* This technology includes a novel advancement in developing vaccines targeting norovirus, tailored specifically for a more robust and effective response. It centers around an improved version of Virus-Like Particles (VLPs) uniquely engineered for greater stability and efficacy. These enhanced VLPs are designed to remain intact even when faced with the body's immune responses, overcoming a key limitation of previous vaccine designs. This stability is crucial in ensuring the vaccine's effectiveness, particularly in individuals with more robust immune systems who have shown limited response to traditional vaccines. Additionally, the modified VLPs are likely more resistant to degradation, making them a more reliable and durable solution in vaccination campaigns. This innovation could be a significant step in offering a more effective vaccine option for widespread use.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

*Potential Commercial Applications:*

- *Enhanced Norovirus Vaccination:* Specially designed to improve the effectiveness of vaccines against norovirus, particularly in individuals with previously low response rates to traditional vaccines.
- *Broad-Scale Immunization Programs:* Suitable for large-scale public health initiatives due to its increased