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.