[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: Dianca Finch, Ph.D., 240-669-5503; dianca.finch@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows:

A High-Yield Perfusion-Based Transient Gene Expression Bioprocess.

Description of Technology:

Currently, fed-batch processes are the most commonly used bioprocesses in transient gene expression (TGE) vaccine manufacturing. However, because fed-batch processes keep all the cells and protein product in the vessel throughout the run, some limitations are intrinsic. First, waste products like cell debris or other unwanted small molecules accumulate in the vessel with a potential to disrupt the cell growth, protein production, and the stability of the generated protein of interest. Second, necessary buffer exchange and/or cell concentration steps must be performed outside of the culturing vessel. These steps are more involved and increase the risk of contamination. Lastly, even with the addition of daily supplementation in the fed-batch process, there are limitations in length of time that the transfected cells remain viable and productive.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) developed a new transient gene expression (TGE) bioprocess using a perfusion system that resolves the current fed-batch limitations for influenza vaccine production. The major components of this technology are two-fold: the optimization of conditions for polyethylenimine (PEI)-mediated gene transfection in the bioreactor without the interference of microbubbles; and the implementation of a perfusion-based alternating tangential flow (ATF) system for single-system, prolonged cell culture, combining the steps of cell concentration, waste clearance, culturing/media replenishment, and protein expression within a single vessel.

The development of the TGE bioprocess included optimization of conditions for HEK293 cell growth in the bioreactor, optimized transfection mediated by PEI, and protein expression for an extended period to achieve reproducibility and high protein yield.

Due to high improvement in cell growth and protein production without external handling, this bioprocess could lead to substantial cost saving and other benefits in vaccine and drug manufacturing of clinical grade materials.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404.

Potential Commercial Applications:

- Bioprocess- A single-use protein production platform for transient gene expression (TGE) with potential applications in rapid protein expression as well as vaccine and drug manufacturing.

Competitive Advantages:

The new transient gene expression (TGE) bioprocess for vaccine manufacturing has the following features compared to commonly used related processes such as fed-batch:

- Robust, prolonged cell growth.
- High levels of protein production and reproducibility.
- Cost efficiency.
- Reduction in contamination risk.

Development Stage: Final Product.

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Blackstock, PhD (NIAID); and Joe Horwitz, PhD (NIAID).

Intellectual Property: HHS Reference Number E-187-2018 includes U.S. Provisional Patent Application Number 62/751,204 filed 10/26/2018.

Licensing Contact: To license this technology, please contact Dianca Finch, Ph.D., 240-669-5503; dianca.finch@nih.gov.

Dated: October 10, 2019.

Wade W. Green,

Acting Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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