



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Pigment Epithelium-Derived Factor (PEDF) Peptides and Use for Treating Retinal Degeneration

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Eye Institute, an institute of the National Institutes of Health, United States Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice to Perpetual Biosciences, Inc., a company located in New York, NY.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center, representing the National Eye Institute, on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Geoffrey E. Ravilious, Ph.D., NCI Technology Transfer Center, Telephone: 240-276-6391; E-mail: geoffrey.ravilious@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 63/430,251 filed December 5, 2022, entitled "PIGMENT EPITHELIUM-DERIVED FACTOR PEPTIDES AND USE FOR TREATING RETINAL DEGENERATION" [HHS Reference No. E-028-2023-0-US-01];
2. International Patent Application PCT/US2024/064947 filed March 24, 2023, entitled "PIGMENT EPITHELIUM-DERIVED FACTOR PEPTIDES AND USE FOR TREATING RETINAL DEGENERATION" [HHS Reference No. E-028-2023-0-PCT-01]; and

3. Australian Patent No. 2023390868 issued June 5, 2025, entitled “PIGMENT EPITHELIUM-DERIVED FACTOR PEPTIDES AND USE FOR TREATING RETINAL DEGENERATION” [HHS Reference No. E-028-2023-0-AU-01];
4. Canadian Patent Application No. 3,275,801 effective filing date of June 3, 2025, entitled “PIGMENT EPITHELIUM-DERIVED FACTOR PEPTIDES AND USE FOR TREATING RETINAL DEGENERATION” [HHS Reference No. E-028-2023-0-CA-01];
5. European Patent Application No. 23720018.3 filed July 1, 2025, entitled “PIGMENT EPITHELIUM-DERIVED FACTOR PEPTIDES AND USE FOR TREATING RETINAL DEGENERATION” [HHS Reference No. E-028-2023-0-EP-01];
6. Japanese Patent Application No. 2025-555099 effective filing date of June 4, 2025, entitled “PIGMENT EPITHELIUM-DERIVED FACTOR PEPTIDES AND USE FOR TREATING RETINAL DEGENERATION” [HHS Reference No. E-028-2023-0-JP-01];
7. United States Patent No. 19/135,668, entitled “PIGMENT EPITHELIUM-DERIVED FACTOR PEPTIDES AND USE FOR TREATING RETINAL DEGENERATION” [HHS Reference No. E-028-2023-0-US-02].
8. United States Provisional Patent Application No. 63/604,026 filed November 29, 2023, entitled “MODIFIED PIGMENT EPITHELIUM-DERIVED FACTOR PEPTIDES AND METHODS OF USE” [HHS Reference No. E-028-2023-0-US-01]; and
9. PCT Patent Application No. PCT/US2024/057784 filed November 27, 2024, entitled “MODIFIED PIGMENT EPITHELIUM-DERIVED FACTOR PEPTIDES AND METHODS OF USE” [HHS Reference No. E-028-2023-0-PCT-01];
10. any and all other U.S. and ex-U.S. patents and patent applications claiming priority to any one of the foregoing, now or in the future.

The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the following:

“Peptide therapeutics for human ophthalmological diseases that may include but not be limited to retinitis pigmentosa, glaucoma, or age-related macular degeneration.”

This technology describes chemically synthesized peptide fragments derived from PEDF, a naturally occurring neurotrophic factor that is produced by retinal pigment epithelia. The biological roles of PEDF suggest that peptide fragments of PEDF have the potential to treat multiple diseases that fall within the Field of Use. Efforts to utilize native PEDF for therapeutic effect, as well as many invasive gene therapy approaches, have had minimal effect on outcomes for patients with ophthalmic diseases that result from neurodegeneration or retinal cell death. The subject invention potentially addresses the limited efficacy of approved therapeutic treatments for ophthalmic diseases that result from neurodegenerative pathologies and/or retinal cell death.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Eye Institute, receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: March 30, 2026.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

