



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of BL-760 Dye for Intraoperative Fluorescence Imaging

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the patents and patent applications listed in the Supplementary Information section of this notice to OptoSurgical LLC (“OptoSurgical”), a company located in Columbia, Maryland, the United States of America.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center 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 applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Lauren Nguyen-Antczak, Ph.D., J.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (301)-624-8752; E-mail: lauren.nguyen-antczak@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. PCT Application No. PCT/US2014/064136 filed November 5, 2014, entitled "A New Class of Stable Heptamethine Cyanine Fluorophores And Biomedical Applications Thereof" [HHS Reference No. E-271-2014-0-PCT-01].

2. United States Patent No. 10,280,307 (Application No. 15/524,567) filed May 4, 2017, entitled "A New Class of Stable Heptamethine Cyanine Fluorophores And Biomedical Applications Thereof" [HHS Reference No. E-271-2014-0-US-02].
3. United States Patent No. 10,876,003 (Application No. 16/374,642) filed April 3, 2019, entitled "A New Class of Stable Heptamethine Cyanine Fluorophores And Biomedical Applications Thereof" [HHS Reference No. E-271-2014-0-US-03].
4. PCT Application No. PCT/US2019/018153 filed February 15, 2019, entitled "A New Class of Stable Heptamethine Cyanine Fluorophores And Biomedical Applications Thereof" [HHS Reference No. E-046-2019-0-PCT-01].
5. United States Patent No. 10,961,193 (Application No. 16/969,902) filed August 13, 2020, entitled "A New Class of Stable Heptamethine Cyanine Fluorophores And Biomedical Applications Thereof" [HHS Reference No. E-046-2019-0-US-06].
6. United States Patent No. 11,746,086 (Application No. 17/179,217) filed February 18, 2021, entitled "A New Class of Stable Heptamethine Cyanine Fluorophores And Biomedical Applications Thereof" [HHS Reference No. E-046-2019-0-US-07].
7. United States Patent Application No. 18/520,027 filed November 27, 2023, entitled "A New Class of Stable Heptamethine Cyanine Fluorophores And Biomedical Applications Thereof" [HHS Reference No. E-046-2019-1-US-01].
8. PCT Application No. PCT/US2019/018057 filed February 14, 2019, entitled "Heptamethine Cyanines For Use As Fluorescent Markers Of The Biliary And Renal Systems" [HHS Reference No. E-036-2018-0-PCT-01].
9. United States Patent Application No. 18/358,068 filed July 25, 2023, entitled "Heptamethine Cyanines For Use As Fluorescent Markers Of The Biliary And Renal Systems" [HHS Reference No. E-036-2018-0-US-03].

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 the “United States,” and the field of use may be limited to the following:

“Development, manufacture and commercialization of BL-760 dye as disclosed and claimed in the Licensed Patent Rights for Intraoperative fluorescence imaging to visualize the bile duct and small biliary structures, including gallbladder, during hepato-pancreato-biliary surgery in humans.”

The E-271-2014-0 and E-046-2019-0 patent families are primarily directed to a new class of stable heptamethine cyanine fluorophores and biomedical applications thereof, including near-infrared fluorescent contrast agents for intraoperative fluorescence imaging. The E-036-2018-0 patent family is primarily directed to heptamethine cyanines for use as fluorescent markers of the biliary and renal systems, including methods of intraoperative visualization of biliary structures using such agents.

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 Cancer 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.

“This Notice is made in accordance with 35 U.S.C. 209(e) and 37 C.F.R. §404 Authority to grant exclusive licenses.”

Dated: August 7, 2026.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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