



This document is scheduled to be published in the Federal Register on 04/06/2016 and available online at <http://federalregister.gov/a/2016-07864>, and on FDsys.gov

[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License for Commercialization: Boron Neutron Capture Therapy for Skin Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a worldwide exclusive license to practice the inventions embodied in: HHS Ref. No. E-135-2015/0, U.S. Provisional Patent Application No. 62/155,085, filed April 30, 2015, entitled “Boron Mimics Of Amino Acids And Uses Thereof,” to Beijing Lanyears Communication Technology, Ltd., a company formed under the laws of the People’s Republic of China and having its principle place of business in Beijing, China.

The contemplated exclusive license may be limited to boron neutron capture therapy for skin cancer.

DATES: Only written comments and/or applications for a license that are received by NIH at the address indicated below on or before **[INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for a copy of any unpublished patent application, inquiries, objections to this notice, comments and other requests relating to the contemplated license should be directed to: Michael

Shmilovich, Esq., CLP, Senior Licensing and Patent Manager, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479, phone number 301-435-5019, or shmilovm@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The invention pertains to boramino acid compounds that can be used as imaging agents for positron emission tomography of cancer or for boron neutron capture therapy. Mimetics created by substituting the carboxylate group (-COO-) of an amino acid with trifluoroborate (-BF₃-) are metabolically stable and allow for the use of fluorine-18 (¹⁸F) as the radiolabel (e.g., trifluoroborate phenylalanine (B-Phe)). Using boramino acid for ¹⁸F-labeling allows for integrating the ¹⁸F radiolabel into the core molecular backbone rather than the side-chains thus increasing the agent's target specificity. There is a direct relationship between amino acid uptake and cancer cell replication, where the uptake is extensively upregulated in most cancer cells. This uptake increases as cancer progresses, leading to greater uptake in high-grade tumors and metastases. Amino acids act as signaling molecules for proliferation and may also reprogram metabolic networks in the buildup of biomass. This invention provides for an unmet need for traceable amino acid mimics, including those based on naturally-occurring amino acids, which may be non-invasively detected by imaging technology, including for clinical diagnosis or BNCT. Boron neutron capture therapy (BNCT) is based on the nuclear capture and fission reactions that occur when non-radioactive boron-10 (¹⁰B, approximately 20% of natural elemental boron), is irradiated and thus activated with neutrons of the appropriate energy to yield excited boron-11 (¹¹B*). This isotope then decays into high energy alpha particles ("stripped" down ⁴He nuclei) and high energy lithium-7 (⁷Li) nuclei. Both the emitted alpha particles and the lithium ions are close proximity reactions, i.e., at a range of approximately 5–9 μm; the diameter of a target cell. The energies produced in this ionization and radio-decay is cytotoxic and thus exploited as the basis for cancer radiotherapy. The success of BNCT is dependent on the selective delivery of sufficient amounts of ¹⁰B to the tumor site with only small amounts localized in the surrounding normal tissues thus sparing normal tissue from the nuclear capture and fission reactions.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. § 209 and 37 CFR § 404.7. The prospective exclusive license may be granted

unless, within fifteen (15) days from the date of this published notice, NIH 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 § 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. § 552.

Dated: April 1, 2016.

Michael Shmilovich,
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Office of Technology Transfer and Development,
National Heart, Lung, and Blood Institute.

[FR Doc. 2016-07864 Filed: 4/5/2016 8:45 am; Publication Date: 4/6/2016]