

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 brain tumors.

**DATES:** Only written comments and/or applications for a license that are received by NIH at the address indicated below on or before April 21, 2016 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**ADDRESSES:** Requests for a copy of any unpublished patent application, inquiries, objections to this notice, comments and other requests relating to the contemplated license should be directed to: Michael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](mailto: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 (-BF<sub>3</sub>-) are metabolically stable and allow for the use of fluorine-18 (<sup>18</sup>F) as the radiolabel (e.g., trifluoroborate phenylalanine (B-Phe)). Using boramino acid for <sup>18</sup>F-labeling allows for integrating the <sup>18</sup>F 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 (<sup>10</sup>B, approximately 20% of natural elemental boron), is irradiated and thus activated with neutrons of the appropriate energy to yield excited boron-11 (<sup>11</sup>B\*). This isotope turn decays into high energy alpha particles ("stripped" down <sup>4</sup>He nuclei) and high energy lithium-7 (<sup>7</sup>Li) 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 <sup>10</sup>B 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,**

*Senior Licensing and Patent Manager, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute.*

[FR Doc. 2016-07865 Filed 4-5-16; 8:45 am]

**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 April 21, 2016 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](mailto:shmilovm@mail.nih.gov).

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decays into high energy alpha particles ("stripped" down  $^4\text{He}$  nuclei) and high energy lithium-7 ( $^7\text{Li}$ ) nuclei. Both the emitted alpha particles and the lithium ions are close proximity reactions, *i.e.*, at a range of approximately 5–9  $\mu\text{m}$ ; 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  $^{10}\text{B}$  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**,  
*Senior Licensing and Patent Manager, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute.*

[FR Doc. 2016-07864 Filed 4-5-16; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

[Docket No. DHS-2016-0027]

#### Privacy Act of 1974; Department of Homeland Security, U.S. Customs and Border Protection, DHS/CBP-014 Regulatory Audit Archive System (RAAS) System of Records

**AGENCY:** Privacy Office, Department of Homeland Security.

**ACTION:** Notice of Privacy Act System of Records.

**SUMMARY:** In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to

update and reissue a current DHS system of records titled, "DHS/U.S. Customs and Border Protection (CBP)-014 Regulatory Audit Archive System (RAAS) System of Records" (73 FR 77807, December 19, 2008). This system of records allows DHS/CBP to collect and maintain records on individuals subject to regulatory audits of customs brokers, importers, and other parties involved in international trade activities. CBP is updating this system of records notice to reflect changes to its authorities, category of records, and routine uses. Specifically, these changes include expanding the category of records to permit the collection of Employer Identification Numbers (EINs) or Social Security numbers (SSNs), also known as a Federal Taxpayer Identifying Number, and business records associated with the audit from customs brokers, importers, and other parties via merchandise entry documentation. CBP is clarifying the authorities section to include updated and more narrowly tailored authorities to permit the collection of EIN or SSN. CBP is making non-substantive edits to the Routine Uses A–G to align with previously published Departmental Systems of Records Notices (SORNs). Lastly, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice.

Additionally, DHS is issuing a Notice of Proposed Rulemaking to reduce the current exemptions for this system of records from certain provisions of the Privacy Act elsewhere in the **Federal Register**. The previously issued Final Rule for DHS/CBP-014 RAAS (Aug. 31, 2009, 74 FR 45076) remains in effect until a new Final Rule is issued. This updated system will be included in the DHS inventory of record systems.

**DATES:** Submit comments on or before May 6, 2016. This updated system will be effective May 6, 2016.

**ADDRESSES:** You may submit comments, identified by docket number DHS-2016-0027 by one of the following methods:

- *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-343-4010.

- *Mail:* Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received, please visit <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** For general questions, please contact: John Connors, (202) 344-1610, Privacy Officer, U.S. Customs and Border Protection, Privacy and Diversity Office, 1300 Pennsylvania Ave. NW., Washington, DC 20229. For privacy questions, please contact: Karen L. Neuman, (202) 343-1717, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP) proposes to update and reissue a current DHS system of records titled, "DHS/CBP-014 Regulatory Audit Archive System (RAAS) System of Records."

DHS/CBP conducts regulatory audits in support of its oversight of customs brokers licensed by DHS/CBP pursuant to 19 U.S.C. 1641 to act as agents for importers in the entry of merchandise and payment of duties and fees. This system of records covers records about importers and other parties engaged in international trade activities that are the subject of a regulatory audit or are identified in and related to the scope of an audit report.

As a result of a biennial review of this SORN, DHS/CBP is updating the categories of records to include the collection of EINs or SSNs, also known as Federal Taxpayer Identifying Number, pursuant to 19 CFR 24.5, 19 CFR 149.3, and E.O. 9397, *as amended* by E.O. 13478. DHS/CBP collects this additional data to align RAAS with information provided by importers through the DHS/CBP Automated Commercial Environment System (ACE) data-source. DHS/CBP is also clarifying the category of records to include business and audit records collected or created as part of the audit process.

DHS/CBP is clarifying the authorities section to include updated and more narrowly tailored authorities to permit the collection of EIN or SSN. 19 CFR 24.5 and 19 CFR 149.3 require that DHS/CBP collect Federal Taxpayer Identifying Numbers in association with services resulting in issuance of a bill or refund check upon adjustment of a cash collection or to document entities that are liable for payment of all duties and