

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of V-ATPase Inhibitor Compounds for the Treatment of Human Cancers and Osteoclastic Bone Diseases Excluding Rheumatoid Arthritis and Other Osteo-Specific Auto-Immune Diseases

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that 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 following U.S. Patents and Patent Applications to the Australian Institute of Marine Science ("AIMS") located in Townsville, Queensland, Australia.

Intellectual Property

- U.S. Provisional Patent Application No. 60/398,092 filed July 24, 2002 entitled "Chondropsin-Class Antitumor V-ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E-191-2002/0-US-01];
- International Patent Application No. PCT/US03/23290 filed July 24, 2003 entitled "Chondropsin-Class Antitumor V-ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E-191-2002/0-PCT-02];
- U.S. Patent Application No. 10/521,930 filed April 18, 2005 entitled "Chondropsin-Class Antitumor V-ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E-191-2002/0-US-03];
- European Patent Application No. 03751813.1 filed February 16, 2005 entitled "Chondropsin-Class Antitumor V-ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E-191-2002/0-EP-04];
- Australian Patent Application No. 2003269924 filed February 4, 2005 entitled "Chondropsin-Class Antitumor V-ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E-191-2002/0-AU-05];
- Canadian Patent Application No. 2493821 filed January 24, 2005 entitled "Chondropsin-Class Antitumor V-ATPase Inhibitor Compounds,

Compositions and Methods of Use Thereof" [HHS Ref. No. E-191-2002/0-CA-06];

- U.S. Patent No. 7,521,475 issued April 21, 2009 entitled "Chondropsin-Class Antitumor V-ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E-191-2002/0-US-07];
- U.S. Patent Application No. 12/402,560 filed March 12, 2009 entitled "Chondropsin-Class Antitumor V-ATPase Inhibitor Compounds, Compositions and Methods of Use Thereof" [HHS Ref. No. E-191-2002/0-US-08];
- U.S. Provisional Patent Application No. 60/220,270 filed July 24, 2000 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E-203-2000/0-US-01];
- International Patent Application No. PCT/US01/23633 filed July 24, 2001 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E-203-2000/0-PCT-02];
- US Patent No. 7,144,918 issued December 5, 2006 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E-203-2000/0-US-04];
- US Patent Application No. 11/435,189 filed May 16, 2006 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E-203-2000/0-US-08];
- Australian Patent No. 200112808 issued November 30, 2006 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E-203-2000/0-US-03];
- European Patent Application No. 01959257.5 filed July 24, 2001 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E-203-2000/0-EP-05];
- Canadian Patent Application No. 2415611 filed July 24, 2001 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E-203-2000/0-CA-06]; and
- Japanese Patent Application No. 514137/2002 filed July 24, 2001 entitled "Biologically Active Macrolides, Compositions, and Uses Thereof" [HHS Ref. No. E-203-2000/0-JP-07].

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

The prospective exclusive license territory may be worldwide and the field of use may be for "use of Licensed Patent Rights for use and development of pharmaceutically suitable V-ATPase Inhibitor compounds for the treatment of human cancers, including osteosarcoma, and osteoclastic bone diseases, such as osteoporosis, osteopenia and Paget's disease," in "all"

geographic territories. For avoidance of doubt, the field of use will specifically exclude rheumatoid arthritis and other osteo-specific autoimmune diseases.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before February 12, 2010 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Sabarni K. Chatterjee, PhD Licensing and Patenting Associate, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5587; Facsimile: (301) 435-4013; e-mail: chatterjeesa@od.nih.gov.

SUPPLEMENTARY INFORMATION: The technology describes the class of Chondropsin compounds and its derivatives. The compounds can be potentially developed into new therapeutics for cancer, osteoporosis, and Alzheimer's diseases.

Briefly, vacuolar type (H+) ATPase (V-ATPase) has been described as "a universal proton pump of eukaryotes". V-ATPase is responsible for maintaining internal acidity and is important in myriad of physiological functions, such as sorting of membrane proteins, proinsulin conversion, neurotransmitter uptake, and cellular degradation process. This technology describes a new chondropsin, Poecillastrin-A, a cytotoxic, 33-member ring, macrolide lactam, isolated from the sponge *Poecillastra* sp. It is structurally related to the chondropsin class of macrolide lactams. However, it possesses unique patterns of methylation and oxygenation, and it is the first member of this family of polyketide derivatives with a 33-membered macrocyclic ring. The in vitro anti-tumor activity of the compound is comparable to that of the chondropsins, however the new structural features found in Poecillastrin-A broaden the known structural diversity of this family of potent anti-proliferative and cytotoxic macrolide lactams. The chondropsins and poecillastrin A produce a distinctive pattern of differential cytotoxicity in the NCI's 60 cell antitumor screen that directly correlates with selective V-ATPase inhibitors.

This class of compounds and its derivatives have the potential of being used as a therapeutics against several cancer types and may have applicability as highly selective anti-cancer small molecule inhibitors. Additionally, it has

the potential of being used for the treatment of several other diseases such as osteoporosis, and Alzheimer's diseases.

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 part 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the 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 part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted 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: December 29, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2010-420 Filed 1-12-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection

Activities: Accreditation of Commercial Laboratories and Approval of Commercial Gaugers

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Extension of an existing information collection: 1651-0053.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Accreditation of Commercial Laboratories and Approval of Commercial Gaugers. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected

agencies. This proposed information collection was previously published in the **Federal Register** (74 FR 58036) on November 10, 2009, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before February 12, 2010.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to oir_submission@omb.eop.gov or faxed to (202) 395-5806.

SUPPLEMENTARY INFORMATION: U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104-13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

Title: Accreditation of Commercial Laboratories and Approval of Commercial Gaugers.

OMB Number: 1651-0053.

Form Number: None.

Abstract: Commercial gaugers and laboratories seeking accreditation or approval must provide the information specified in 19 CFR 151.12 and/or 19 CFR 151.13 to CBP. CBP uses this information in deciding whether to approve individuals or businesses desiring to measure bulk products or to analyze importations

Current Actions: There are no changes to the information collection. This

submission is being made to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Businesses, Individuals.

Reporting

Estimated Number of Respondents: 200.

Estimated Number of Responses per Respondent: 1.

Estimated Number of Total Responses: 200.

Estimated Time per Response: 75 minutes.

Estimated Total Burden Hours: 250.

Recordkeeping

Estimated Number of Recordkeepers: 200.

Estimated Time per Recordkeeper: 60 minutes.

Estimated Total Burden Hours: 200.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229-1177, at 202-325-0265.

Dated: January 7, 2009.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2010-464 Filed 1-12-10; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2009-0299]

Terminate Long Range Aids to Navigation (Loran-C) Signal

AGENCY: U.S. Coast Guard, DHS.

ACTION: Notice; correction.

SUMMARY: The Coast Guard is correcting a notice that appeared in the **Federal Register** of January 7, 2010 (75 FR 998). The document announced termination of the Long Range Aids to Navigation (Loran-C) Signal commencing on or about February 8, 2010. The document had an incorrect word in the **DATES** section.

DATES: Effective January 13, 2010.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, contact Mr. Mike Sollosi, U.S. Coast Guard, Department of Homeland Security, telephone (202) 372-1545, Mike.M.Sollosi@uscg.mil.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 7, 2010, in